REED SMITH LLP
506 Carnegie Center, Suite 300
Princeton, New Jersey 08540
Princeton, New Jersey 08540
Telephone: (609) 987-0050
Facsimile: (609) 951-0824

Attorneys for Defendants
Allergan Inc. and Allergan USA, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921(BRM)(JAD)** **MDL No. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' MASTER PERSONAL INJURY COMPLAINT AND CONSOLIDATED CLASS ACTION COMPLAINT ON PREEMPTION GROUNDS

TABLE OF CONTENTS

Page

I. INTRODUCTION....1
II. STANDARD OF REVIEW....4
III. STATEMENT OF THE CASE....5
A. The FDA Comprehensively Regulates All Aspects Of Class III And Class II Medical Devices Before, During, And After Approval....5
B. FDA Approved Allergan's Class III Breast Implants And Cleared Allergan's Class II Tissue Expanders For Safety And Efficacy, And Continued To Regulate Them After Approval And Clearance....10
C. Plaintiffs' Personal Injury And Medical Monitoring Lawsuits Challenge The Design, Manufacture, Labelling, And Post-Sale Reporting For Allergan's Breast Implants And Tissue Expanders....14
IV. LEGAL ARGUMENT....16
A. Federal Preemption Principles Foreclose Virtually All State Law Product Liability And Tort Claims Relating To The Design, Manufacture, Labelling and Reporting For FDA Approved And Cleared Medical Devices....16
B. Plaintiffs' Warning Claims Involving Allergan's Class III Breast Implants Are Expressly And Impliedly Preempted....22
1. All Warning Claims Based On Allegations That The FDA-Required Warnings Are Inadequate Are Expressly Preempted....23
2. All Warning Claims Couched As A Failure To Report Adverse Events To FDA Are Expressly Preempted....25
3. All Warning Claims Based On The Method For Adverse Event Reporting Are Expressly Preempted....30
4. All Warning Claims Relating To Reporting Are Impliedly Preempted....31
C. Plaintiffs' Claims Alleging That Allergan Should Have Submitted A "Changes Being Effected" Supplement For Its Warnings Are Expressly Preempted....35
D. Plaintiffs' Claims Challenging Allergan's Post-Sale Clinical Studies Are Expressly Preempted....38

E. Plaintiffs' "Manufacturing Defect" Claims Attacking Allergan's PMA-Approved Manufacturing Process Are Expressly Preempted.....39

1. Plaintiffs Do Not Allege Any Deviation From FDA Manufacturing Specifications So Express Preemption Applies 40

2. Plaintiffs' Allegations That All Textured Breast Implants Are Defective As Manufactured Are Expressly Preempted 43

F. Plaintiffs' Claims Based In Whole Or In Part On "Adulteration" Are Impliedly Preempted 45

G. Plaintiffs' Negligence Per Se Claims Are Impliedly Preempted 47

H. Plaintiffs' Claims Involving Allergan's Class II Style 153 And McGhan RTV Implants Are Preempted.....51

1. PMA Preemption Applies To IDE Medical Devices 52

2. PMA Preemption Applies To Reclassified PMA Medical Devices ...54

V. CONCLUSION 56

TABLE OF AUTHORITIES

Page(s)

Cases

Aaron v. Medtronic, Inc.,
209 F. Supp. 3d 994 (S.D. Ohio 2016) 26, 28

Allen v. Zimmer Holdings, Inc.,
2015 WL 6637232 (D. Nev. Oct. 30, 2015) 55

Barnes v. Howmedica Osteonics Corp.,
2010 WL 11565343 (N.D. Ala. Dec. 14, 2010) 45

Becker v. Optical Radiation Corp.,
66 F.3d 18 (2d Cir. 1995) 53

Becker v. Smith & Nephew, Inc.,
2015 WL 268857 (D.N.J. Jan. 20, 2015).....43

Billetts v. Mentor Worldwide, LLC,
2019 WL 4038218 (C.D. Cal. Aug. 27, 2019) 21

Brooks v. Howmedica, Inc.,
273 F.3d 785 (8th Cir. 2001) 55

Brooks v. Mentor Worldwide, LLC,
2019 WL 4628264 (D. Kan. Sept. 23, 2019).....*passim*

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001).....*passim*

Burgos v. Satiety, Inc.,
2010 WL 4907764 (E.D.N.Y. Nov. 30, 2010) 52

Burrell v. Bayer Corp.,
260 F. Supp. 3d 485 (W.D.N.C. 2017) 34, 40

Bush v. Goren,
2014 WL 4160245 (Mich. App. Aug. 21, 2014) 53

Cales v. Medtronic, Inc.,
2014 WL 6600018 (Ky. Cir. Nov. 21, 2014) 27, 35

Cales v. Medtronic, Inc.,
2017 WL 127731 (Ky. App. June 8, 2017) 27

Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.,
273 F.3d 536 (3d Cir. 2001) 29

Caplinger v. Medtronic, Inc.,
784 F.3d 1335 (10th Cir. 2015) 17, 19

Caplinger v. Medtronic, Inc.,
921 F. Supp. 2d 1206 (W.D. Okla. 2013).....19

Cashen v. Johnson & Johnson,
2018 WL 6809093 (New Jersey Super. L.D. Dec. 24, 2018).....21

Chambers v. Osteonics Corp.,
109 F.3d 1243 (7th Cir. 1997) 53

Chester v. Boston Scientific Corp.,
2017 WL 751424 (D.N.J. Feb. 27, 2017) 20, 27, 34, 43

City of Philadelphia v. Beretta U.S.A. Corp.,
277 F.3d 415 (3d Cir. 2002) 29

Clements v. Sanofi-Aventis, U.S., Inc.,
111 F. Supp. 3d 586 (D.N.J. 2015).....20, 24

Cmty. Nutrition Inst. v. Young,
818 F.2d 943 (D.C. Cir. 1987).....45

Coba v. Ford Motor Co.,
932 F.3d 114 (3d Cir. 2019) 43, 44

Conklin v. Medtronic, Inc.,
431 P.3d 571 (Ariz. 2018) 25, 30, 33

Cornett v. Johnson & Johnson,
211 N.J. 362, 48 A.3d 1041 (2012) .....*passim*

Cornett v. Johnson & Johnson,
414 N.J. Super. 365, 998 A.2d 543 (A.D. 2010) 49

Cornwell v. Stryker Corp.,
2010 WL 4641112 (D. Idaho Nov. 1, 2010) 46

Couvillier v. Allergan, Inc.,
2011 WL 8879258 (W.D. La. Jan. 20, 2011) 21

Couvillier v. Allergan, Inc.,
2011 WL 8879259 (W.D. La. Feb. 9, 2011) 21

D'Addario v. Johnson & Johnson,
2020 WL 3546750 (D.N.J. June 30, 2020).....*passim*

Day v. Howmedica Osteonics Corp.,
2015 WL 13469348 (D. Colo. Dec. 24, 2015) 54

De La Paz v. Bayer Healthcare LLC,
159 F. Supp. 3d 1085 (N.D. Cal. 2016).....46, 47

Delaney v. Stryker Orthopaedics,
2009 WL 564243 (D.N.J. March 5, 2009).....42

Diodato v. Mentor Worldwide LLC,
2020 WL 3402296 (D. Md. June 19, 2020).....21

Doe v. Bausch & Lomb, Inc.,
__ F. Supp. 3d __, 2020 WL 1164189 (D. Conn. March 11, 2020).....19

Dorsey v. Allergan, Inc.,
2009 WL 703290 (M.D. Tenn. March 11, 2009) 21, 54

Dunbar v. Medtronic, Inc.,
2014 WL 3056026 (C.D. Cal. June 25, 2014).....51

Dzielak v. Whirlpool Corp.,
26 F. Supp. 3d 304 (D.N.J. 2014).....4

Ebrahimi v. Mentor Worldwide LLC,
2017 WL 4128976 (C.D. Cal. Sept. 15, 2017) 21, 39

Ebrahimi v. Mentor Worldwide LLC,
2018 WL 2448095 (C.D. Cal. May 25, 2018).....21, 28

Ebrahimi v. Mentor Worldwide LLC,
2018 WL 6829122 (C.D. Cal. Dec. 27, 2018).....21

Ebrahimi v. Mentor Worldwide LLC,
804 F. App'x 871 (9th Cir. 2020) 21, 28

English v. Bayer Corp.,
__ F. Supp. 3d __, 2020 WL 3454877 (W.D.N.Y. June 25, 2020) 27

Erie R.R. Co. v. Thompkins,
304 U.S. 64, 78 (1938).....29

Franklin v. Medtronic, Inc.,
2010 WL 2543579 (D. Colo. May 12, 2010) 50

Franklin v. Medtronic, Inc.,
2010 WL 2543570 (D. Colo. June 22, 2010) 51

Funk v. Stryker Corp.,
631 F.3d 777 (5th Cir. 2011) 40

Gile v. Optical Radiation Corp.,
22 F.3d 540 (3d Cir. 1994) 45, 46, 52, 53

Gomez v. Bayer, Corp.,
2018 WL 10612946 (N.J. Super. L.D. Aug. 31, 2018) 20, 24

Gomez v. Bayer Corp.,
2020 WL 215897 (N.J. Super. A.D. Jan. 14, 2020) 20, 32

Grant v. Corin Group PLC,
2016 WL 4447523 (S.D. Cal. Jan. 15, 2016) 51, 54

Green v. Medtronic, Inc.,
2019 WL 7631397 (N.D. Ga. Dec. 31, 2019) 50

Gross v. Stryker Corp.,
858 F. Supp. 2d 466 (W.D. Pa. 2012).....19

Gupta v. Wipro Ltd.,
749 F. App'x 94 (3d Cir. 2018) 4

Hackett v. G.D. Searle & Co.,
246 F. Supp. 2d 591 (W.D. Tex. 2002) 51

Hafer v. Medtronic, Inc.,
99 F. Supp. 3d 844 (W.D. Tenn. 2015) 50

Hannan v. Boston Sci. Corp.,
2020 WL 2128841 (N.D. Cal. May 5, 2020).....42

Harduvel v. General Dynamics Corp.,
878 F.2d 1311 (11th Cir. 1989) 42

Hart v. Medtronic, Inc.,
2017 WL 5951698 (D.N.J. Nov. 30, 2017) 20, 24

Hayes v. Endologix, Inc.,
__ F. Supp. 3d __, 2020 WL 1624022 (E.D. Ky. March 26, 2020) 50

Heckler v. Chaney,
470 U.S. 821 (1985).....9

Horn v. Thoratec Corp.,
376 F.3d 163 (3d Cir. 2004) 20

In re Agent Orange Prod. Liab. Litig.,
517 F.3d 76 (2d Cir. 2008) 44

In re Avandia Mktg. Sales Practices & Prod. Liab. Litig.,
588 F. App'x 171 (3d Cir. 2014) 4

In re Bard IVC Filters Prod. Liab. Litig.,
2017 WL 5625548 (D. Ariz. Nov. 22, 2017) 50

In re Bard IVC Filters Prod. Liab. Litig.,
2018 WL 4356638 (D. Ariz. Sept. 12, 2018) 50

In re Bard IVC Filters Prod. Liab. Litig.,
2018 WL 1256768 (D. Ariz. March 12, 2018).....49, 50

In re Burlington Coat Factory Sec. Litig.,
114 F.3d 1410 (3d Cir. 1997) 4

In re Coordinated Latex Glove Litig.,
121 Cal. Rptr. 301 (Cal. App. 2002).....42

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.,
592 F. Supp. 2d 1147 (D. Minn. 2009).....37, 46, 47, 54

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.,
623 F.3d 1200 (8th Cir. 2010) .....*passim*

In re Orthopedic Bone Screw Prod. Liab. Litig.,
193 F.3d 781 (3d Cir. 1999) 48, 52

In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.,
401 F. Supp. 3d 538 (D. Md. 2019).....38, 39

In re Zimmer NexGen Knee Implant Prod. Liab. Litig.,
884 F.3d 746 (7th Cir. 2018) 25

Jacob v. Mentor Worldwide, LLC,
389 F. Supp. 3d 1024 (M.D. Fla. 2019).....21, 28

Jacob v. Mentor Worldwide, LLC,
2019 WL 6766574 (M.D. Fla. Dec. 10, 2019) 21

Jacob v. Mentor Worldwide, LLC,
393 F. Supp. 3d 912 (C.D. Cal. 2019) 21, 28, 34

Jahn v. Comm'r, IRS,
392 F. App'x 949 (3d Cir. 2010) 36

Kapps v. Biosense Webster, Inc.,
813 F. Supp. 2d 1128 (D. Minn. 2011).....50

Killen v. Stryker Spine,
2012 WL 4498865 (W.D. Pa. Sept. 28, 2012).....54

Lake v. Kardjian,
874 N.Y.S.2d 751 (N.Y. Sup. 2008).....35

Latimer v. Medtronic, Inc.,
2015 WL 5222644 (Ga. Super. Sept. 4, 2015) 27, 35

Laux v. Mentor Worldwide, LLC,
2017 WL 5186329 (C.D. Cal. Nov. 8, 2017) 21

Laux v. Mentor Worldwide, LLC,
786 F. App'x 84 (9th Cir. 2019) 21

Leo v. Kerr-McGee Chem. Corp.,
37 F.3d 96 (3d Cir. 1994) 29

Leonard v. Medtronic, Inc.,
2011 WL 3652311 (N.D. Ga. Aug. 19, 2011) 50, 51

Lewkut v. Stryker Corp.,
724 F. Supp. 2d 648 (S.D. Tex. 2010) 46

Lindler v. Mentor Worldwide LLC,
2014 WL 6390307 (D.S.C. Oct. 23, 2014) 21

Littlebear v. Advanced Bionics,
896 F. Supp. 2d 1085 (N.D. Okla. 2012) 35

Lopez v. Davis,
531 U.S. 230 (2001) 36

Loreto v. Procter & Gamble Co.,
515 F. App'x 576 (6th Cir. 2013) 19

Malonzo v. Mentor Worldwide, LLC,
2014 WL 2212235 (N.D. Cal. May 28, 2014) 21, 28

Marmol v. St. Jude Med. Ctr.,
132 F. Supp. 3d 1359 (M.D. Fla. 2015) 27, 29

Marsh v. Genentech, Inc.,
693 F.3d 546 (6th Cir. 2012) 33

Martin v. Medtronic, Inc.,
2017 WL 825410 (E.D. Cal. Feb. 24, 2017) 45, 46

Martin v. Telectronics Pacing Systems, Inc.,
105 F.3d 1090 (6th Cir. 1997) 53

McGookin v. Guidant Corp.,
942 N.E.2d 831 (Ind. App. 2011) 37

McNeil-Williams v. DePuy Orthopaedics, Inc.,
384 F. Supp. 3d 570 (E.D.N.C. May 292019) 27

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996) 6, 18

Mendez v. Shah,
94 F. Supp. 3d 633 (D.N.J. 2015) 43

Miller v. United Techs. Corp.,
660 A.2d 810 (Conn. 1995) 42

Millman v. Medtronic, Inc.,
2015 WL 778779 (D.N.J. Feb. 24, 2015) 20

Mink v. Smith & Nephew, Inc.,
860 F.3d 1319 (11th Cir. 2017) 33

Morton v. Allergan, Inc.,
2015 WL 12839493 (D.N.J. April 2, 2015) 20, 24, 43

Mullins v. Ethicon, Inc.,
2017 WL 275452 (S.D.W. Va. Jan. 19, 2017) 50

Nicholson v. Pickett,
2016 WL 854370 (M.D. Ala. March 4, 2016) 42

Norabuena v. Medtronic, Inc.,
86 N.E.3d 1198 (Ill. App. 2017) 26, 29

Norman v. Bayer Corp.,
2016 WL 4007547 (D. Conn. July 26, 2016) 26, 50

Oliver v. Oshkosh Truck Corp.,
911 F. Supp. 1161 (E.D. Wis. 1996) 42

Oliver v. Oshkosh Truck Corp.,
96 F.3d 992 (7th Cir. 1996) 42

Ortiz v. Allergan, Inc.,
2015 WL 5178402 (S.D.N.Y. Sept. 4, 2015) 21

Parker v. Stryker Corp.,
584 F. Supp. 2d 1298 (D. Colo. 2008).....46

Parks v. Howmedica Osteonics Corp.,
2016 WL 7220707 (M.D. Fla. March 11, 2016) 53

Pearsall v. Medtronics, Inc.,
147 F. Supp. 3d 188 (E.D.N.Y. 2015) 34

Perdue v. Wyeth Pharmaceuticals, Inc.,
209 F. Supp. 3d 847 (E.D.N.C. 2016) 50

Perez v. Nidek Co.,
711 F.3d 1109 (9th Cir. 2013) 45

Phillips v. Medtronic, Inc.,
2012 WL 3641487 (Mass. Super. July 10, 2012).....35

Potolicchio v. Medtronic, Inc.,
2016 WL 3129186 (E.D. Tenn. June 2, 2016) 27

Purchase v. Advanced Bionics, LLC,
896 F. Supp. 2d 694 (W.D. Tenn. 2011) 46

Ramirez v. Medtronic, Inc.,
961 F. Supp. 2d 977 (D. Ariz. 2013) 50

Riegel v. Medtronic, Inc.,
451 F.3d 104 (2d Cir. 2006) 7, 17

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008).....*passim*

Ries v. Nat'l R.R. Passenger Corp.,
960 F.2d 1156 (3d Cir. 1992) 47

Riley v. Cordis Corp.,
625 F. Supp. 2d 769 (D. Minn. 2009).....19, 37

Robinson v. Endovascular Techs., Inc.,
119 Cal. Rptr. 3d 158 (Cal. App. 2010).....52

Roll v. Tracor, Inc.,
102 F. Supp. 2d 1200 (D. Nev. 2000).....42

Rowe v. Mentor Worldwide LLC,
297 F. Supp. 3d 1288 (M.D. Fla. 2018).....28, 49

Russell v. Johnson & Johnson,
S.W.2d, 2018 WL 5851101 (Ky. Ct. App. Nov. 9, 2018).....53

Sadler v. Advanced Bionics, Inc.,
929 F. Supp. 2d 670 (W.D. Ky. 2013).....46

Salinero v. Johnson & Johnson,
400 F. Supp. 3d 1334 (S.D. Fla. 2019).....42

Scanlon v. Medtronic Sofamor Danek USA Inc.,
61 F. Supp. 3d 403 (D. Del. 2014).....27

Schouest v. Medtronic, Inc.,
13 F. Supp. 3d 692 (S.D. Tex. 2014).....50

Scott v. Pfizer Inc.,
249 F.R.D. 248 (E.D. Tex. 2008) 55

Sewell v. Mentor Worldwide, LLC,
2019 WL 4038219 (C.D. Cal. Aug. 27, 2019) 21

Sharp v. St. Jude Med., S.C., Inc.,
396 F. Supp. 3d 1250 (N.D. Ga. 2019).....50

Shelp v. Allergan, Inc.,
2018 WL 6694287 (W.D. Wash. Dec. 20, 2018) 21

Sheridan v. NGK Metals Corp.,
609 F.3d 239 (3d Cir. 2010) 29

Shuker v. Smith & Nephew, PLC,
885 F.3d 760 (3d Cir. 2018) 17, 18, 20, 24

Sikkelee v. Precision Airmotive Corp.,
907 F.3d 701 (3d Cir. 2018) 26, 31, 32

Slater v. Optical Radiation Corp.,
961 F.2d 1330, 1333-34 (7th Cir. 1992).....53

Smith v. Depuy Orthopaedics, Inc.,
2013 WL 1108555 (D.N.J. March 18, 2013).....20, 24, 43

Smith v. Depuy Orthopaedics, Inc.,
552 F. App'x 192 (3d Cir. 2014) 20

Spizzirri v. Zyla Life Scis.,
802 F. App'x 738 (3d Cir. 2020) 4

Stampley v. Allergan USA, Inc.,
2019 WL 1604201 (W.D. La. March 15, 2019) 21

Stampley v. Allergan USA, Inc.,
2019 WL 1601613 (W.D. La. April 15, 2019) 21

Starks v. Coloplast Corp.,
2014 WL 617130 (E.D. Pa. Feb. 18, 2014) 55

Stengel v. Medtronic, Inc.,
704 F.3d 1224 (9th Cir. 2013) (en banc) 29, 36, 37

Talley v. Danek Med., Inc.,
179 F.3d 154 (4th Cir. 1999) 48

Thibodeau v. Cochlear Ltd.,
2014 WL 3700868 (D. Ariz. July 25, 2014).....50

Thompson v. Depuy Orthopaedics, Inc.,
2015 WL 7888387 (S.D. Ohio Dec. 4, 2015).....55

Tinkler v. Mentor Worldwide, LLC,
2019 WL 7291239 (S.D. Fla. Dec. 30, 2019).....21, 28

Travelers Indem. Co. v. Dammann & Co.,
594 F.3d 238 (3d Cir. 2010) 29

Vanderklok v. United States,
868 F.3d 189 (3d Cir. 2017) 4

Vieira v. Mentor Worldwide, LLC,
392 F. Supp. 3d 1117 (C.D. Cal. 2019) 21, 28, 34

Walker v. Medtronic, Inc.,
670 F.3d 569, 580-81 (4th Cir. 2012) 43

Webb v. Mentor Worldwide LLC,
__ F. Supp. 3d __, 2020 WL 1685323 (N.D.N.Y. April 7, 2020).....21, 28

Weber v. Allergan, Inc.,
WL 9817168 (D. Ariz. Jan. 25, 2018) 21

Weber v. Allergan, Inc.,
940 F.3d 1106 (9th Cir. 2019) 21

Werwinski v. Ford Motor Co.,
286 F.3d 661 (3d Cir. 2002) 29

White v. Medtronic, Inc.,
2019 WL 1339613 (E.D. Mich. Feb. 20, 2019).....27

White v. Medtronic, Inc.,
808 F. App'x 290 (6th Cir. 2020) 27

Williams v. Allergan USA, Inc.,
2009 WL 3294873 (D. Ariz. Oct. 14, 2009).....21, 54

Williams v. Cyberonics, Inc.,
388 F. App'x 169 (3d Cir. 2010) 20, 40

Williams v. Mentor Worldwide LLC,
2019 WL 4750843 (N.D. Ohio Sept. 30, 2019) 21

Williams v. Smith & Nephew, Inc.,
123 F. Supp. 3d 733 (D. Md. 2015).....38

Zaccarello v. Medtronic, Inc.,
38 F. Supp. 3d 1061 (W.D. Mo. 2014).....50

Statutes

21 U.S.C. §332 9

21 U.S.C. §333(f)(1)(A) 9

21 U.S.C. § 334(a)(2)(D) 9

21 U.S.C. §337(a) ..... *passim*

21 U.S.C. §360c(a)(1)(B) 6

21 U.S.C. §360c(a)(1)(C) 6

21 U.S.C. §360c(a)(2)(C) 7

21 U.S.C. §360e(d)) 6, 7

21 U.S.C. §360j(e)(1) 7

21 U.S.C. §360j(g) 12, 52

21 U.S.C. §360k 6, 37

21 U.S.C. §360k(a) ..... *passim*

21 U.S.C. §360k(a)(1) 18

N.J.S.A. 2A:58C-2 44

Regulations

21 C.F.R. §360h 8

21 C.F.R. §803.50(a) 8

21 C.F.R. §803.50(b)(3) 8

21 C.F.R. §807.87 6

21 C.F.R. §812 52

21 C.F.R. §814.20(b) 7

21 C.F.R. §814.39 8

21 C.F.R. §814.39(a).....36

21 C.F.R. §814.39(d) 35, 37

21 C.F.R. §814.39(e)(2).....36

21 C.F.R. §814.80 7

21 C.F.R. §814.82 7

21 C.F.R. §814.84(b) 8

21 C.F.R. §820.70 15

21 C.F.R. §820.70, et seq. 15

21 C.F.R. §820.100 15

21 C.F.R. §861.1(b)(3).....7

53 Fed. Reg. 23856, 23862 (1988) 10

Other Authorities

FDA, Manufacturer & User Facility Device Experience Database – (MAUDE) (2020), https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude 28

FDA, Medical Device Reporting (MDR): How To Report Medical Device Problems (2019), https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.....28

FDA, Summary Reporting of Medical Device Adverse Events (1997), https://web.archive.org/web/20000914063243/http:/www.fda.gov/cdrh/offerlet.html 30

https://web.archive.org/web/20010915235609/http://www.fda.gov/cdrh/breastimplants/indexbip.PDF 11

https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer 12

https://rarediseases.info.nih.gov/diseases/3112/anaplastic-large-cell-lymphoma 1

H.R. Rep. No. 94-853 (1976) 17

Restatement (Second) of Torts §288B(1) (1965) 47

S. Rep. No. 94-33 (1975) 5, 6

I. INTRODUCTION

In this MDL proceeding, Plaintiffs' Master Complaints allege that Allergan's breast implant devices are defectively designed and manufactured because they either caused them to develop, or placed them at increased risk of developing, anaplastic large cell lymphoma ("ALCL").[1] Plaintiffs also contend that Allergan knew of this risk but failed to adequately warn of it or downplayed the risk in its reporting to FDA. All of this, in turn, allegedly violates FDA regulations and breaches duties of care under state product liability or tort law. Here, however, Plaintiffs' frontal attack on the design, manufacture and labelling of these devices, as well as Allergan's post-marketing reporting, runs squarely into federal preemption principles established by settled law. Dismissal of these claims therefore is called for and respectfully requested.

Allergan's breast implants are Class III Medical devices subject to FDA's highest level of scrutiny under the FDA's Pre-Market Approval ("PMA") process. Before selling any Class III device, manufacturers, like Allergan, must establish that their device is safe and effective for its intended use. This is not a perfunctory exercise. The scrutiny FDA applies is comprehensive, rigorous, and continuous. FDA looks at every aspect of design, manufacture, and labelling before a device is marketed. This same rigorous oversight extends post-approval, including with respect to adverse event reporting on a device's use after sale. Moreover, before,

[1] ALCL is a type of non-Hodgkin lymphoma, classified as a "rare cancer" by the National Institutes of Health. "Anaplastic large cell lymphoma," available at < https://rarediseases.info.nih.gov/diseases/3112/anaplastic-large-cell-lymphoma >.

during and after sale, manufacturers are not permitted to deviate from what FDA's regulations require. If they do, they face corrective measures, including fines and civil penalties as specifically set forth in the controlling regulatory scheme.

To protect the efficacy and vitality of FDA's regulation and oversight over medical devices, Congress enacted an express preemption provision that forecloses state interference with the regulatory process. The provision specifically provides that: "[N]o State may establish or continue in effect" any laws or regulations that are "different from, or in addition to, any requirement" applicable to medical devices under the federal scheme. 21 U.S.C. §360k(a). And to further ensure that no such interference occurs, Congress also prohibits private enforcement of the implementing statutes and regulations and instead required all "proceedings for the enforcement, or to restrain violations" to be brought by the United States. 21 U.S.C. §337(a).

As case after case has held, in their combined effect, these two statutory provisions expressly or impliedly preempt virtually all state law product liability and tort claims, including those that Plaintiffs advance in this MDL. In fact, with respect to breast implant devices specifically, courts have routinely applied these preemptive principles to dismiss claims similar to the ones Plaintiffs are making. The same result should follow here.

In a handful of instances, certain state law claims have survived a preemption defense where there is no demonstrable conflict with the regulatory scheme. For example, if the record shows that a device, as manufactured, deviates from its FDA-approved design, a manufacturing defect claim can be made when permitted under

state law. Other state law claims based on duties imposed by federal regulations are possible, but only if an established state law duty parallels what federal regulations require. Alleged non-compliance with federal regulations alone will not do it—no private plaintiff can bring such a claim, only the federal government. Nor will a breach allegedly founded on an alteration or change in what federal regulations otherwise require—any such allegations impermissibly command something different than what federal law requires.

As these preemptive principles illustrate, the gap left for state law claims over FDA-approved and -cleared medical devices is a narrow one and Plaintiffs' claims, as alleged, do not fit through it. Plaintiffs do not allege that Allegan's devices deviated from their intended design. And there is no established state law that supports the breaches of duty they do allege—whether related to Allergan's devices' design, manufacture, labelling, or its reporting post-sale. On the contrary, Plaintiffs' state law product liability and tort claims improperly challenge the FDA-approved design, manufacture, and labelling and reporting related to Allergan's medical devices. And they just as impermissibly allege breaches of duties founded exclusively on federal regulations with no counterpart duties reflected in state law. Express and implied preemption principles unequivocally bar such claims. There is no relevant case law holding otherwise.

For the reasons set forth more fully below, this Court should grant Allergan's motion and dismiss all claims related to Allergan devices that were subject to the

PMA process.[2] *See, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) ("*Sprint Fidelis II*") (affirming grant of motion to dismiss disposing of all product liability claims in MDL involving PMA medical device).

II. STANDARD OF REVIEW

For this motion, the Court accepts as true all "well-pleaded factual allegations and matters subject to judicial notice, but it "need not credit a complaint's bald assertions or legal conclusions." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429 (3d Cir. 1997). Courts also do not accept allegations "contradicted by exhibits attached to the complaint or matters subject to judicial notice." *Gupta v. Wipro Ltd.*, 749 F. App'x 94, 97 (3d Cir. 2018); *see Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 319 (D.N.J. 2014) (on a motion to dismiss, court "may consider … items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case"). Official FDA documents on the FDA's website may be judicially noticed. *See Spizzirri v. Zyla Life Scis.*, 802 F. App'x 738, 739 (3d Cir. 2020); *In re Avandia Mktg. Sales Practices & Prod. Liab. Litig.*, 588 F. App'x 171, 174 n.14 (3d Cir. 2014); *see also Vanderklok v. United States*, 868 F.3d

[2] The order of dismissal should extend to all claims related to devices that received FDA approval through the PMA process, and also devices that (1) FDA reclassified to PMA status, or (2) were the subject of research during the PMA process under the Investigational Device Exception ("IDE"), but never approved. Once the preempted claims are dismissed, the only non-preempted claims alleged concern: (1) non-PMA tissue expanders that were only used for a limited number of indications, and then for only short periods of time, and (2) possibly a few pre-PMA RTV® implants, if any plaintiff was actually implanted with such a device.

189, 205 n.16 (3d Cir. 2017) (the "information is publicly available on government websites and therefore we take judicial notice").

III. STATEMENT OF THE CASE

A. The FDA Comprehensively Regulates All Aspects Of Class III And Class II Medical Devices Before, During, And After Approval

This motion to dismiss rests on the FDA's regulatory process governing Class III and Class II medical devices. That process is reflected in a comprehensive and detailed set of statutes and regulations that are intended, by Congressional mandate, to regulate every aspect of medical device manufacture and marketing in order to maintain the safety and efficacy of the regulated devices, free of state law interference.[3]

For many years, medical devices were designed, manufactured, marketed, and sold without extensive federal regulatory oversight. By 1976, policymakers and the public had become concerned about the lack of federal control because, by that time, "many devices [we]re so intricate that skilled healthcare professionals [we]re unable to ascertain whether they [we]re defective" and "[i]ncreasing numbers of patients [were] exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." S. Rep. No. 94-33, at 2 (1975).

In response, Congress enacted the Medical Device Amendments ("MDA") to the existing Food, Drug, and Cosmetic Act ("FDCA"), which gave FDA authority to ensure that all medical devices were safe and effective before entering the

[3] The history and effect of this regulatory effort are chronicled in the many preemption cases cited in this motion.

marketplace. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) ("*Lohr*") (citing 90 Stat. 539); S. Rep. No. 94-33, at 1. The MDA was, and is, intended to strike a careful balance between "the benefits that medical research and experimentation to develop devices offers to mankind" and "the need for regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices." S. Rep. No. 94-33, at 6.

To achieve the requisite balance, the MDA established three categories of medical devices, identified respectively as Class I, II, or III, "depending on the risks they present." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Class I devices present the lowest risk and are subject to the least intensive regulation. Class II devices pose intermediate risk (CT scanners, blood tests and prosthetic devices) and are subject to greater general and specific regulatory controls. Before a manufacturer can market Class II medical devices, FDA must clear them through the Section 510(k) process. *See* 21 U.S.C. §360(k). Class II devices cannot be cleared through that process unless they are found to be safe and effective under established regulatory requirements. *See* 21 U.S.C. §360c(a)(1)(B); 21 C.F.R. §807.87.

Class III devices receive the most scrutiny. Because Class III devices are "of substantial importance in preventing impairment to human health," but also pose "unreasonable risk of illness or injury," they are subject to the strictest controls. 21 U.S.C. §360c(a)(1)(C). Before marketing a Class III medical device, the manufacturer must submit a PMA application that FDA can grant "only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323 (citing 21 U.S.C. §360e(d)).

PMA applications are exhaustive. They must include "full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) ("*Riegel II*"), *aff'd*, 552 U.S. 312 (2008); *see also* 21 C.F.R. §814.20(b) (specifying PMA application requirements). "Before deciding whether to approve the application, the [FDA] may refer it to a panel of outside experts [citation], and may request additional data from the manufacturer." *Riegel*, 552 U.S. at 318. "FDA spends an average of 1,200 hours reviewing each application" and "must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id.* (quoting 21 U.S.C. §360c(a)(2)(C)).

As part of its review, FDA can condition approval on adherence to performance standards and impose restrictions on sale or distribution, or compliance with other requirements. It can also impose device-specific requirements by regulation. *Id.* at 319 (citing 21 U.S.C. §§360e(d), 360j(e)(1); 21 C.F.R. §§814.82, 861.1(b)(3)). These conditions are mandatory and exacting. An approved Class III device "may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. §814.80. To that end, manufacturers who wish to change any safety-related aspect of an approved Class

III device (such as its design, warnings, or manufacturing process) must submit a supplemental application to FDA in most instances, unless FDA instructs otherwise. *See* 21 C.F.R. §814.39.

After approval, FDA retains plenary authority to take any additional measures it believes necessary with respect to Class III devices on the market. *See* 21 C.F.R. §360h. These measures include: (1) sending notice to health care professionals, manufacturers, and other affected parties; (2) requiring manufacturers to repair, replace, or refund; or (3) instituting a recall of the device. *See id*. In short, where a medical device "is a PMA device, the FDA continues to monitor and regulate all aspects of the product, including its marketing, labeling and manufacturing." *Cornett v. Johnson & Johnson*, 211 N.J. 362, 378-79, 48 A.3d 1041 (2012) ("*Cornett II*").

As for the continuing regulatory obligations, once a Class III device is on the market, the manufacturer must report about new published or unpublished device-related scientific reports. *See* 21 C.F.R. §814.84(b). It also must report any information that its device "may have caused or contributed to a death or serious injury," or "[h]as malfunctioned and this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. §803.50(a). To comply with these adverse event reporting requirements, the manufacturer is "responsible for conducting an investigation of each event and evaluating the cause of the event." *Id*. §803.50(b)(3).

As noted, Congress intended this regulatory process—before and after approval—to operate free from state interference. To help ensure the exclusivity

and effectiveness of federal oversight, the controlling statutes include an express preemption provision, mandating that: "[N]o State may establish or continue in effect" any laws or regulations that are "different from, or in addition to, any requirement" applicable to medical devices under the federal scheme. 21 U.S.C. §360k(a). By enacting this provision, Congress "swept back some state obligations and imposed a regime of detailed federal oversight," enforced by an expert federal agency rather than private plaintiffs and lay juries. *Riegel*, 552 U.S. at 316.

To further preserve the primacy of the FDA's regulatory authority, however, Congress went a step further. That is, the statutory scheme also expressly prohibits private enforcement. Apart from certain lawsuits that states may initiate, "all such proceedings for the enforcement, or to restrain violations … shall be by and in the name of the United States." 21 U.S.C. §337(a). Congress thus has given FDA "a variety of enforcement options that allow it to make a measured response" to any wrongdoing, including "injunctive relief, 21 U.S.C. §332, and civil penalties, 21 U.S.C. §333(f)(1)(A); seizing the device, §334(a)(2)(D); and pursuing criminal prosecutions, §333(a)." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

Congress likewise granted FDA "complete discretion" in deciding "how and when [these enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Indeed, "[t]his flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349. Accordingly, any attempt by a private plaintiff to sue over a claimed violation of the duties imposed by the federal

regulatory scheme is impliedly preempted by this no private right of action provision. *Id.* at 352-53.

B. FDA Approved Allergan's Class III Breast Implants And Cleared Allergan's Class II Tissue Expanders For Safety And Efficacy, And Continued To Regulate Them After Approval And Clearance

Plaintiffs allege that they developed ALCL, or have a significantly increased risk of developing ALCL, from exposure to Allergan's BIOCELL® breast implants.[4] (Consolidated Class Action Complaint ("CAC") ¶1; Master Long-Form Personal Injury Complaint ("PIC") ¶¶6, 8.) Breast implants generally are used to replace surgically removed breast tissue, to correct developmental defects, or to modify breast size and shape. (CAC ¶99.) They are filled with either saline or silicone gel. (CAC ¶100; PIC ¶5). As designed, Allergan's BIOCELL® breast implants have a textured surface, which is intended to prevent surgical complications after implantation. (CAC ¶1; PIC ¶3.)

FDA oversight of breast implants is decades old. In 1988, FDA reclassified breast implants as Class III devices (PIC ¶48), but required §510(k) clearance, not PMA approval. 53 Fed. Reg. 23856, 23862 (1988). Three years later, in April 1991, FDA declared that all silicone gel-filled breast implants would be subject to PMA approval. Eight years after that, in August 1999, it made the same determination for

[4] Allergan acquired some of the breast implant device lines involved in this litigation from predecessor manufacturers. To avoid confusion, and unless otherwise required, we will use "Allergan" to refer to these manufacturers as well.

saline-filled breast implants. (CAC ¶31; PIC ¶51; *see also* FDA's "Breast Implants—An Information Update—2000"[5].)

In the Master Complaints, Plaintiffs allege exposure to multiple breast implant devices and product lines. The relevant regulatory history is as follows:

- ***Allergan Natrelle® Saline-Filled Breast Implants approved under P990074.*** (CAC ¶2 n.1; PIC ¶41.)

  Allergan submitted a PMA application for this line in November 1999. In May 2000, FDA approved same for use in breast reconstruction procedures in women over 18 years old. (RJN at p. 1; Geist Decl. Exh. 1.) Among its post-approval requirements, FDA required Allergan to conduct and report on certain post-approval studies regarding performance, failure modes, patients' informed decision making, and mechanical testing. (RJN at p. 1; Geist Decl. Exh. 1 (Approval Order).) Allergan submitted forty-four supplemental PMA applications in connection with this device line, with the most recent one approved on July 30, 2020. (RJN at p. 1; Geist Decl. Exh. 2.) This PMA is still in effect.

- ***Allergan Natrelle® Silicone-Filled Textured Breast Implants approved under P020056***. (CAC ¶2 n.1; PIC ¶41.)

  Allergan submitted a PMA application for this line in December 2002. In November 2006, FDA approved same for use in: (1) breast augmentation for women over 22 years old; and (2) breast reconstruction for women of any age. Among its post-approval requirements, FDA required: (1) physicians using the device to complete Allergan's training program; and (2) Allergan to conduct and report on post-approval studies regarding long-term clinical performance, complications and disease, device failure, labeling, and patients' informed decisionmaking (RJN at p. 1; Geist Decl. Exh. 3 (Approval Letter).) Allergan submitted fifty-one supplemental PMA applications in connection with this device line, with the most recent

[5] Available at https://web.archive.org/web/20010915235609/http://www.fda.gov/cdrh/breastimplants/indexbip.PDF (last visited August 6, 2000).

one approved on July 30, 2020. (RJN at p. 1; Geist Decl. Exh. 4.) This PMA is still in effect.

- ***Natrelle®410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046.*** (CAC ¶2 n.1; PIC ¶41.)

  Allergan submitted a PMA application for this line in December 2004. In February 2013, FDA approved same for use in: (1) breast augmentation for women over 22 years old; and (2) breast reconstruction for women of any age. In addition to the standard post-approval requirements, FDA further required Allergan to submit reports from post-approval studies regarding safety and efficacy, long-term clinical performance, rare disease outcomes, labeling, and explant analyses, along with a PMA Core Study that Allergan already had completed. (RJN at p. 2; Geist Decl. Exh. 5 (Approval Letter).) Allergan submitted thirty-two supplemental PMA applications in connection with this device line, with the most recent one approved on July 30, 2020. (RJN at p. 2; Geist Decl. Exh. 6.) This PMA is still in effect.

- ***McGhan BioDIMENSIONAL® Silicone-Filled BIOCELL® Textured Breast Implant, Style 153***. (CAC ¶2 n.1; PIC ¶41.)

  From 1998 to 2006, Allergan's BIOCELL® silicone breast implant line received an Investigative Device Exemption ("IDE"). (CAC ¶115; PIC ¶5 n.3.) An IDE allows a device to be used in strictly regulated clinical trials to collect safety and efficacy data from human test subjects for purposes of obtaining PMA approval or 510(k) clearance. *See* 21 U.S.C. §360j(g). All Style 153 implants were implanted as part of these FDA-regulated clinical trials. (RJN at p. 2; Geist Decl. Exh. 7.) Following the study results, Style 153 implants were discontinued in 2005, FDA approval was not sought, and Style 153 implants were never marketed. (PIC ¶99 n.31; *see* https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer.)

- ***McGhan RTV® Saline-Filled Mammary Implant (implanted before PMA Approval of Allergan Natrelle® Saline-Filled Textured Breast Implant).*** (CAC ¶326.)

In the mid-1980s, these devices were the subject of a Premarket Notification for which FDA granted Section 510(k) clearance. (RJN at p. 2; Geist Decl. Exh. 8; CAC ¶115.) After FDA required saline breast implants to receive PMA approval in 1999, FDA approved the PMA application for these saline implants in May 2000 (RJN at p. 2 n.2; Geist Decl. Exhs. 1-2; CAC ¶118; PIC ¶58).

Plaintiffs also allege exposure to Allergan's BIOCELL® line of tissue expanders. (CAC ¶99; PIC ¶4 n.2.) FDA regulates breast tissue expanders as Class II medical devices. (CAC ¶135.) Tissue expanders are temporary inflatable implants that stretch skin and muscle to create space for breast implants. (CAC ¶99; PIC ¶4.) Allergan's BIOCELL® tissue expanders, like the breast implants in this line, also have a textured surface. (CAC ¶99; PIC ¶4.) Identification of these expanders and their regulatory history is as follows:

- ***Natrelle® 133 Plus Tissue Expander With Suture Tabs***. (CAC ¶¶2 n.1, 326; PIC ¶41.)

  In September 2010, Allergan submitted a Section 510(k) notification for this device, seeking clearance as substantially equivalent to a predicate tissue expander currently on the market. (PIC ¶41 n.19.) In January 2011, FDA cleared it as a Class II device. (PIC ¶52.) FDA reminded Allergan of its ongoing regulatory requirements regarding product registration, labeling, adverse event reporting, good manufacturing practices and quality control systems. (RJN at p. 3; Geist Decl. Exh. 9 (Clearance Letter).)

- ***Natrelle® 133 Plus Tissue Expander***. (CAC ¶¶2 n.1, 326.)

  In July 2015, Allergan submitted a Section 510(k) notification for this device, seeking clearance as substantially equivalent to a predicate tissue expander currently on the market. In August 2015, FDA cleared as a Class II device. (PIC ¶52.) FDA also reminded Allergan of its ongoing regulatory requirements regarding product registration, labeling, adverse event reporting, good manufacturing practices and

quality control systems. (RJN at p. 3; Geist Decl. Exh. 10 (Clearance Letter).)

C. Plaintiffs' Personal Injury And Medical Monitoring Lawsuits Challenge The Design, Manufacture, Labelling, And Post-Sale Reporting For Allergan's Breast Implants And Tissue Expanders

In July 2019, pursuant to an FDA request, Allergan voluntarily recalled various BIOCELL® breast implants and tissue expanders. (CAC ¶191; PIC ¶39.) Litigation followed, resulting in this MDL proceeding. Both Master Complaints allege that Plaintiffs and the putative class were implanted with Allergan's devices and they advance various liability theories that divide into three broad categories:

First, Plaintiffs allege that Allergan concealed the risks of contracting ALCL by failing to comply with various regulatory requirements related to its adverse event reporting, promotional materials, and labelling information. According to Plaintiffs, by 2006, Allergan possessed information and evidence regarding the risks of ALCL, but did not submit timely or adequate adverse event reports to FDA, manipulated data under FDA's "Alternative Summary Report" ("ASR") program, and did not report adverse events risks from the post-approval studies required by FDA. (CAC ¶¶201-220; PIC ¶¶87-95.) Plaintiffs further allege that Allergan downplayed the risk of ALCL in its promotional materials (CAC ¶¶221-26; PIC ¶¶96-105) and failed to revise its product labeling with information regarding ALCL (CAC ¶¶255-265; PIC ¶¶73, 100, 115). These acts purportedly amounted to a "failure to comply" with FDA's "post-approval requirements." (CAC ¶¶262; PIC ¶¶72-73.)

Second, Plaintiffs allege that Allergan's manufacturing process was defective, "result[ing] in an adulterated product." (CAC ¶190; PIC ¶114.) In manufacturing

its breast implants, Allergan utilized a "salt loss" manufacturing process, during which salt particles were embedded into the surface of the implant shell and covered with a layer of silicone. (CAC ¶13; PIC ¶117.) The outer silicone layer was manually scrubbed, and the entire implant shell was washed to remove solid particles. (CAC ¶13; PIC ¶117.) This process allegedly resulted in a textured implant shell intended to prevent growth of excess collagen and fibrous tissue, which in turn kept the implant from hardening and constricting (a condition called capsular contracture). (CAC ¶¶165-68; PIC ¶99.)

Plaintiffs maintain, however, that Allergan's manual scrubbing process—which FDA approved as part of the PMA applications—caused solid particles and residue to remain embedded in the implant shell. (CAC ¶169; PIC ¶¶117-18.) They further assert that the textured surface, combined with the remaining particles and residue, caused an inflammatory response that can ultimately lead to ALCL. (CAC ¶170; PIC ¶¶118-19.) Plaintiffs then allege that this manufacturing process violates various FDA regulations. (CAC ¶¶171-88; PIC ¶119.)

Third, Plaintiffs further claim that Allergan did not satisfy FDA's Current Good Manufacturing Practices ("CGMP"), which require manufacturers to "develop control, and monitor production processes to ensure that a device conforms to its specifications." (CAC ¶176 (citing 21 C.F.R. §820.70).) As described in the Master Complaints, this includes FDA requirements for production process changes, environmental controls, contamination controls, equipment, manufacturing material, automated processes, equipment inspection and testing, manufacturing process

validation, and for implementing corrective action. (CAC ¶¶177-78 (citing 21 C.F.R. §820.70, *et seq.*; CAC ¶180 (citing 21 C.F.R. §820.100).)

Based on these allegations, Plaintiffs advance state law claims for: (1) failure to warn (strict liability and negligence); (2) manufacturing defect (strict liability and negligence); (3) design defect (strict liability and negligence); (4) breach of implied warranty; (5) violations of consumer fraud and deceptive practice statutes; (6) unjust enrichment; (7) declaratory relief; and (8) rescission. A small number of the personal injury Plaintiffs allegedly have developed ALCL. As for the putative class representatives or putative class members who have not, they seek classwide relief in the form of medical monitoring. (CAC ¶269.)

IV. LEGAL ARGUMENT

A. Federal Preemption Principles Foreclose Virtually All State Law Product Liability And Tort Claims Relating To The Design, Manufacture, Labelling And Reporting For FDA Approved And Cleared Medical Devices

Plaintiffs' claims are aimed directly at the FDA's regulatory oversight and, ultimately, at the requirements governing the manufacture, design, distribution, and reporting for Allergan's Class III PMA-approved and Class II cleared breast implants and breast tissue extenders. As a result, Plaintiffs' claims trigger principles of express and implied preemption established by federal law. These preemption principles leave only a narrow gap for state law product liability or tort claims. Plaintiffs' claims, purporting to invoke the law of all 50 states and 6 U.S. territories, do not fit through.

Express preemption. In *Riegel*, the Supreme Court affirmed that federal law expressly preempts state law claims challenging the safety or performance of Class III PMA-approved devices. *See* 552 U.S. at 312. To ensure "innovations in medical device technology are not stifled by unnecessary restrictions," and to prevent "undu[e] burden[]" on device manufacturers from "differing requirements ... imposed by jurisdictions other than the Federal government," Congress adopted §360k(a) as a "general prohibition on non-Federal regulation." *Riegel II*, 451 F.3d at 122 (*quoting* H.R. Rep. No. 94-853, at 12, 45 (1976)). Absent this express prohibition, "additional state duties on top of those imposed by federal law … might check innovation, postpone access to life-saving devices, and impose barriers to entry without sufficient offsetting safety gains." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346 (10th Cir. 2015) (Gorsuch, J.).

In its reasoning and holding, *Riegel* sets forth a two-step express preemption analysis. In the first step, a court must determine whether "the Federal Government has established requirements applicable to" the medical device. *Riegel*, 552 U.S. at 321-22 (citations and quotation marks omitted). In the second, a court then must determine whether a plaintiff's state-law tort claims would impose "requirements with respect to the device that are different from, or in addition to" the federal requirements. *Id.*

Class III devices, like Allergan's breast implants, satisfy *Riegel*'s first step as a matter of law. *Id.* at 322. As the Third Circuit held: "[B]ecause a manufacturer of a Class III device must receive premarket approval, clear federal safety review ..., and thereby satisfy federal requirements applicable to the device, the manufacturer

of that Class III device receives express preemption protection[].” *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 767 (3d Cir. 2018).

As for *Riegel*’s second step, federal law expressly preempts all state law causes of action that impose safety or effectiveness requirements that are “different from, or in addition to’ the requirements FDA imposed through the PMA process. *Riegel*, 552 U.S. at 322 (quoting §360k(a)). Product liability claims targeting the safety and effectiveness of a PMA medical device necessarily are preempted. *Id*. These include “strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the [PMA device].” *Id.* at 320; *see Shuker*, 885 F.3d at 774 (“negligence, strict liability, and breach of implied warranty claims” preempted; plaintiff allowed to discovery on off-label promotion).

“But state laws are not shut out entirely.” *Shuker*, 885 F.3d at 768. “State requirements are [expressly] pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.” *Riegel*, 552 U.S. at 330 (quoting §360k(a)(1)). Established state-law “duties [that] parallel federal requirements” avoid express preemption where they “duplicate[] the federal rule” and thus promote “compl[iance] with identical existing ‘requirements’ under federal law.” *Lohr*, 518 U.S. at 495.

Implied preemption. Implied preemption is the other half of the story. The rationale is straightforward. Under the FDCA enforcement of the statute is expressly left (except for certain state proceedings) to the United States. 21 U.S.C. §337(a). By enacting this no-private-right-of-action provision, Congress “le[ft] no doubt that

it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the" FDCA. *Buckman*, 531 U.S. at 349 n.4. Accordingly, any state-law "claim [that] would not exist if the FDCA did not exist," is impliedly preempted because such claims are "in substance (even if not in form) a claim for violating the FDCA." *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013), *aff'd*, 784 F.3d 1335 (10th Cir. 2015). And therein lies the conflict that gives rise to implied preemption. A private plaintiff's attempt to sue for a violation of the applicable federal regulations runs squarely into the statutory command that the FDCA is to be "enforced" exclusively by the federal government. *Buckman*, 531 U.S. at 352-53.

Express and implied preemption principles as applied. As this analysis portends, for state law product liability and tort claims to survive, they must fit in the narrow gap left by express preemption on the one hand, and implied preemption on the other. *Sprint Fidelis II*, 623 F.3d at 1204; *e.g.*, *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 492-93 (W.D. Pa. 2012). That is to say, the specific "conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). Or as one court recently explained, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such claim would be impliedly preempted under *Buckman*)."

Doe v. Bausch & Lomb, Inc., ___ F. Supp. 3d ___, 2020 WL 1164189, at *6 (D. Conn. March 11, 2020) (quoting *Sprint Fidelis II*, 623 F.3d 1200, 1204) (emphasis in *Sprint Fidelis II*, other citations omitted).

Under controlling case law, one thing is clear: it is exceedingly difficult to fit through the gap. Relying on these preemptive principles, federal courts—including the Third Circuit and this Court—have dismissed product liability and tort lawsuits involving Class III PMA-approved devices on preemption grounds in a variety of contexts and over an endless array of state law claims. *See, e.g.*, *Shuker*, 885 F.3d at 770-77 (affirming PMA preemption of all claims against PMA components of medical device system); *D'Addario v. Johnson & Johnson*, 2020 WL 3546750, at *4-5 (D.N.J. June 30, 2020) (dismissing ALCL breast implant claims as preempted); *Chester v. Boston Scientific Corp.*, 2017 WL 751424, at *6-12 (D.N.J. Feb. 27, 2017) (amended complaint dismissed with prejudice in action involving implantable defibrillator).[6]

Class III breast implant devices are no exception. Nor could they be. Since *Riegel*, twenty-two decisions have found actions advancing state law product

[6] *See Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010); *Smith v. Depuy Orthopaedics, Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014), *affirming*, 2013 WL 1108555, at *8-11 (D.N.J. March 18, 2013) ("*Smith II*"); *Horn v. Thoratec Corp.*, 376 F.3d 163, 169, 179-80 (3d Cir. 2004) (recognizing broad PMA preemption pre-*Riegel*); *Hart v. Medtronic, Inc.*, 2017 WL 5951698, at *4-6 (D.N.J. Nov. 30, 2017); *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 598-602 (D.N.J. 2015); *Morton v. Allergan, Inc.*, 2015 WL 12839493, at *4-5 (D.N.J. April 2, 2015); *Millman v. Medtronic, Inc.*, 2015 WL 778779, at *4-6 (D.N.J. Feb. 24, 2015); *Gomez v. Bayer, Corp.*, 2018 WL 10612946, at *2 (N.J. Super. L.D. Aug. 31, 2018) ("*Gomez I*"), *aff'd*, 2020 WL 215897 (N.J. Super. A.D. Jan. 14, 2020).

liability and tort claims involving breast implant devices preempted in their entirety. Creative efforts to plead around express and implied preemption have failed, one after the other. [7]

[7] *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1111-14 (9th Cir. 2019), *affirming*, 2018 WL 9817168, at *2-3 (D. Ariz. Jan. 25, 2018); *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871 (9th Cir. 2020), *affirming*, 2017 WL 4128976 (C.D. Cal. Sept. 15, 2017), 2018 WL 2448095 (C.D. Cal. May 25, 2018), and 2018 WL 6829122 (C.D. Cal. Dec. 27, 2018); *D'Addario*, 2020 WL 3546750, at *4-5; *Diodato v. Mentor Worldwide LLC*, 2020 WL 3402296, at *2-3 (D. Md. June 19, 2020); *Webb v. Mentor Worldwide LLC*, ___ F. Supp. 3d ___, 2020 WL 1685323, at *4-7 (N.D.N.Y. April 7, 2020); *Jacob v. Mentor Worldwide, LLC*, 393 F. Supp. 3d 912, 923-26 (C.D. Cal. 2019); *Vieira v. Mentor Worldwide, LLC*, 392 F. Supp. 3d 1117, 1128-32 (C.D. Cal. 2019) ("*Jacob Cal.*"); *Jacob v. Mentor Worldwide, LLC*, 389 F. Supp. 3d 1024, 1028-30 (M.D. Fla. 2019), *amended complaint dismissed*, 2019 WL 6766574, at *3 (M.D. Fla. Dec. 10, 2019) ("*Jacob Fla.*"); *Tinkler v. Mentor Worldwide, LLC*, 2019 WL 7291239, at *4-5 (S.D. Fla. Dec. 30, 2019); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843, at *4-6 (N.D. Ohio Sept. 30, 2019); *Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264, at *4-7 (D. Kan. Sept. 23, 2019), *appeal docketed*, No. 19-3240 (10th Cir. Oct. 24, 2019); *Sewell v. Mentor Worldwide, LLC*, 2019 WL 4038219, at *7-10 (C.D. Cal. Aug. 27, 2019); *Billetts v. Mentor Worldwide, LLC*, 2019 WL 4038218, at *7-9 (C.D. Cal. Aug. 27, 2019); *Stampley v. Allergan USA, Inc.*, 2019 WL 1604201, at *3 (W.D. La. March 15, 2019), *adopted*, 2019 WL 1601613 (W.D. La. April 15, 2019); *Shelp v. Allergan, Inc.*, 2018 WL 6694287, at *2 (W.D. Wash. Dec. 20, 2018); *Laux v. Mentor Worldwide, LLC*, 2017 WL 5186329, at *2-4 (C.D. Cal. Nov. 8, 2017), *aff'd*, 786 F. App'x 84 (9th Cir. 2019); *Ortiz v. Allergan, Inc.*, 2015 WL 5178402, at *4-5 (S.D.N.Y. Sept. 4, 2015); *Lindler v. Mentor Worldwide LLC*, 2014 WL 6390307, at *2 (D.S.C. Oct. 23, 2014); *Malonzo v. Mentor Worldwide, LLC*, 2014 WL 2212235, at *2-3 (N.D. Cal. May 28, 2014); *Couvillier v. Allergan, Inc.*, 2011 WL 8879258, at *1 (W.D. La. Jan. 20, 2011), *adopted*, 2011 WL 8879259 (W.D. La. Feb. 9, 2011); *Williams v. Allergan USA, Inc.*, 2009 WL 3294873, at *2-5 (D. Ariz. Oct. 14, 2009) (investigational implant); *Dorsey v. Allergan, Inc.*, 2009 WL 703290, at *5-7 (M.D. Tenn. March 11, 2009) (investigational implant); *Cashen v. Johnson & Johnson*, 2018 WL 6809093, at *7-11 (New Jersey Super. L.D. Dec. 24, 2018).

A synthesis of the reasoning and holdings in these cases reveals the working principles that are dispositive in Allergan's motion to dismiss. These principles are founded on *Riegel* and *Buckman*, they are the principles that make the gap so narrow, and they are the principles that spell the end of the state law product liability and tort claims that are the subject of this motion:

First, to survive a motion to dismiss, the complaint must allege the breach of a duty expressly set forth in federal regulations;

Second, to survive a motion to dismiss, the complaint must show that the duty expressly set forth in the federal regulations has a parallel counterpart in an established state law duty of care; and

Third, to survive a motion to dismiss, the complaint must make clear that the breach of duty alleged under state law is not based solely on a federal regulatory duty, without regard to state law.

Application of these three immutable principles dictates the outcome of this motion. When the Master Complaints' allegations are analyzed, their warning and product defect theories, whether in strict liability or negligence, fail under one or more of these principles. The claims either: (i) do not show a violation of federal law; (ii) have no counterpart in established state law; or (iii) are based solely on federal duties of care. Preemption is called for in these circumstances.

B. Plaintiffs' Warning Claims Involving Allergan's Class III Breast Implants Are Expressly And Impliedly Preempted

Plaintiffs advance a litany of warning-based claims couched in various guises in an effort to find a gap in the preemptive principles established by settled federal

law. They purport to attack the adequacy of Allergan's FDA-approved warnings, the content of its FDA-mandated reporting, or the method of reporting itself—all as required by federal regulations and Allergan's PMA approval. To the extent these warning claims attempt to nullify or alter what FDA otherwise has required, they are expressly preempted. Further, to the extent these warning claims are based on duties not found in settled state law, they likewise are expressly preempted. And finally, to the extent these claims are based solely on a purported violation of federal regulations, they are impliedly preempted. From any perspective, therefore, Plaintiffs' warning-based claims must be dismissed.

1. All Warning Claims Based On Allegations That The FDA-Required Warnings Are Inadequate Are Expressly Preempted

Plaintiffs' attacks on the adequacy of Allergan's FDA-approved labels are aimed at the content of the disclosures, the risks disclosed, and the manner in which those risks are disclosed.[8] If these claims took hold, they plainly would require something different from, or in addition to, what the controlling regulations mandate. These claims accordingly cannot survive express preemption and must be dismissed.

The Supreme Court in *Riegel* squarely held that §360k(a) "pre-empt[s] a jury determination that the FDA-approved labeling for a [PMA device] violated a state common-law requirement for additional warnings." 552 U.S. at 329. Claims that "have the effect of establishing a substantive requirement for a specific device, *e.g.*,

[8] The adequacy allegations are found in Plaintiffs' claims aimed at the content of Allergan's FDA-approved labelling, as well as at the promotional materials that are consistent with this labelling. (CAC ¶ 264, PIC ¶ 73.) Plaintiffs therefore are suing over what the FDA chose to require in exercising its regulatory role.

a specific labeling requirement" are preempted as "different from, or in addition to, a federal requirement." *Id.* (citation and quotation marks omitted).

In the wake of *Riegel*, courts uniformly have held that preemption bars product liability claims attacking FDA-approved labeling for Class III devices. That is true whether claims attack the disclosures FDA has approved or whether they would require an addition in some fashion to what the FDA has called for. These kinds of claims "impose different requirements on the [device], as [they] seek to impose liability because defendants did not accompany their product with proper warnings regarding the risks associated with a premarket-approved device." *Shuker*, 885 F.3d at 775. They are, simply put, "a challenge to the adequacy of the information required by FDA during the PMA process and label approved by the agency." *Cornett II*, 211 N.J. at 389, 48 A.3d at 1056; *see also Clements*, 111 F. Supp. 3d at 601 (warning-related claims are "tantamount to a requirement that [defendant] must do something 'different from, or in addition to' what the FDA had already approved"); *Hart*, 2017 WL 5951698, at *5 ("Plaintiff is bringing into question the … warning specifications that the FDA approved and requires for this Class III medical device…. This is precisely what §360k(a) preempts."); *accord*, *Morton*, 2015 WL 12839493, at *3; *Smith*, 2013 WL 1108555, at *8-9; *Gomez I*, 2018 WL 10612946, at *2.

There is no basis to depart from this unanimous case law for the warning claims attacking the adequacy of Allergan's FDA-approved labelling, any other FDA-approved communication or publication, or Allergan's promotional materials that are consistent with the FDA-approved labelling. Plaintiffs' claims are no

different than in the dozens of other lawsuits where express preemption has been applied since *Riegel*, including those involving breast implant devices. Dismissal is required here, too.

2. All Warning Claims Couched As A Failure To Report Adverse Events To FDA Are Expressly Preempted

Plaintiffs also base their failure to warn claims on Allergan's alleged failure to adequately report adverse events to FDA. As Plaintiffs would have it, Allergan's failure to make proper adverse event reports to FDA supposedly breached a state law duty to warn physicians about the potential risks of ALCL.[9] These claims fail under established express preemption principles.

Without conceding that Allergan's reporting failed to comply with FDA requirements in any respect, there is a fundamental problem with all of Plaintiffs' allegations tied to such reporting, no matter how couched or framed. The problem is that there is no parallel state tort duty to report to a federal regulatory agency and no way to construe state law duties to warn implanting physicians as giving rise to such a duty.[10] There is thus nothing parallel on which to base a state law duty in

[9] There are a variety of allegations purporting to support how Allergan fell short in the timing of its disclosures, the content in them and data and content in its reports and in its labelling and promotional materials. (CAC ¶¶ 221, PIC ¶ 96.) Allergan's labelling is FDA-approved and its promotional materials were consistent with that labelling. Plaintiffs' quarrel again is with what FDA required.

[10] Virtually all states recognize the learned intermediary doctrine, which "holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 751-52 (7th Cir. 2018) (finding appellate authority for learned intermediary doctrine in 48 states). But "FDA is not a health care provider and does not prescribe anything for patients,"

order to avoid express preemption. In that regard, *Riegel* and the cases applying its reasoning make clear that for a state law claim to avoid preemption, it must be grounded in existing state law. The non-preempted parallel state claim cannot be a made-for-litigation invention. But Plaintiff's failure to report allegations are just that. They are invented for this MDL proceeding and they have no grounding in state law. There is no common law "failure to report to a federal agency" tort claim.

Norabuena v. Medtronic, Inc., 86 N.E.3d 1198 (Ill. App. 2017) is typical of cases addressing the "failure to report" duty issue. In *Norabuena*, the court found that a state-law duty to warn a physician "is not synonymous with an affirmative duty to warn a federal regulatory body." *Id.* at 1207. "[A]lthough plaintiffs have identified a federal requirement that their complaint alleges [defendant] violated, there is no [state] requirement that parallels it." *Id.* at 1206. The reason is that "[t]here is no general or background duty under [state] law to report risks to a regulatory body"—that duty typically runs "to the plaintiff herself[.]" *Norman v. Bayer Corp.*, 2016 WL 4007547, at *4 (D. Conn. July 26, 2016).

But *Norabuena* and *Norman* are hardly alone. Federal courts around the country, including the Third Circuit, have held these sorts of failure to report to a federal agency claims to be expressly preempted because they have no counterpart grounding in state law and there is no parallel claim to be made. *See, e.g.*, *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 716-17 (3d Cir. 2018) (failure-to-report theory improperly "attempted to use a federal duty and standard of care as the basis

---

so it cannot be a "learned intermediary" entitled to receive product warnings under state law. *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018).

for [a] state-law negligence claim"); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016) ("the federal duty *to report certain information to the FDA* is not "identical" and thus not parallel, to the state-law duty *to provide warnings to patients or their physicians*") (emphasis original); *Potolicchio v. Medtronic, Inc.*, 2016 WL 3129186, at *4 (E.D. Tenn. June 2, 2016) ("Tennessee law requires manufacturers to warn physicians, but not the FDA"); *English v. Bayer Corp.*, ___ F. Supp. 3d ___, 2020 WL 3454877, at *3 (W.D.N.Y. June 25, 2020) ("[A] standalone claim [for] 'failure to report adverse events to the FDA' is not a cognizable cause of action under New York law."), *appeal docketed*, No. 20-2137 (2d Cir. July 7, 2020); *Chester*, 2017 WL 751424, at *10 (reporting-based claims assert federal requirements and thus "are expressly preempted"); *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 412 (D. Del. 2014) (claims based on failure to report adverse events to FDA cannot be parallel because "such conduct would not exist apart from the FDCA").[11]

[11] And the list goes on: *McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 575 (E.D.N.C. May 292019) ("North Carolina law does not recognize a parallel duty on manufacturers to report to the FDA"); *White v. Medtronic, Inc.*, 2019 WL 1339613, at *6 (E.D. Mich. Feb. 20, 2019) (FDA reporting requirement "has no state law analog, and thus there is no parallel state cause of action"), *adopted*, 2019 WL 1330923 (E.D. Mich. March. 25, 2019), *aff'd*, 808 F. App'x 290 (6th Cir. 2020), *cert. pending*; *Marmol v. St. Jude Med. Ctr.*, 132 F. Supp. 3d 1359, 1370 (M.D. Fla. 2015) ("Florida law lacks a parallel duty to file adverse reports with the FDA"); *Latimer v. Medtronic, Inc.*, 2015 WL 5222644, at *9 (Ga. Super. Sept. 4, 2015) (allegations "cannot support a parallel claim because there is no duty under Georgia law to report adverse events to the FDA"); *Cales v. Medtronic, Inc.*, 2014 WL 6600018, at *10 (Ky. Cir. Nov. 21, 2014) (holding failure-to-report claims expressly preempted as not "parallel" or "genuinely equivalent" to extant state law), *aff'd*, 2017 WL 127731 (Ky. App. June 8, 2017).

And here again, breast implant device cases are no exception. They too hold there is no state law duty to warn FDA. *See D'Addario*, 2020 WL 3546750, at *5 ("Plaintiffs identify no separate state law duty to warn the FDA.") (citation omitted); *Webb*, 2020 WL 1685323, at *5-6; *Jacob Cal.*, 393 F. Supp. 3d at 925; *Vieira*, 392 F. Supp. 3d at 1130-31; *Jacob Fla.*, 389 F. Supp. 3d at 1029; *Tinkler*, 2019 WL 7291239, at *5; *Brooks*, 2019 WL 4628264, at *5-6; *Rowe v. Mentor Worldwide LLC*, 297 F. Supp. 3d 1288, 1295-96 (M.D. Fla. 2018); *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *2-3 (C.D. Cal. May 25, 2018), *aff'd*, 804 F. App'x 871 (9th Cir. 2020); *Malonzo*, 2014 WL 2212235, at *3.

Brooks, 2019 WL 4628264, sets forth the controlling preemption analysis for Allergan's devices. There, the district court ruled that Plaintiffs' "indirect" warning claim arising from an alleged failure to report was expressly preempted. *Id.* at *6. First, the claim was entirely "speculative" because it "assumed" that FDA would have publicized unreported adverse events, which "it is not required to do."[12] *Id.*

[12] Adverse-event reports themselves "are not warnings." *Aaron*, 209 F. Supp. 3d at 1005. Rather, they are inherently unreliable anecdotes. FDA admits that its own regulations require reporting of "incomplete, inaccurate, untimely, unverified, or biased data." *See* FDA, Medical Device Reporting (MDR): How To Report Medical Device Problems (2019), https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems. FDA cautions that these reports are "not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices" and "do[] not necessarily reflect a conclusion by the party submitting the report by FDA ... that the device ... caused or contribute to the reportable event." FDA, Manufacturer & User Facility Device Experience Database – (MAUDE) (2020), https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude.

But "[e]ven if these allegations were not speculative," they were preempted because "[p]laintiffs have not identified any state law that required [defendant] to report adverse events to the FDA." *Id.* Thus, "like their other claims relating to FDA reporting, plaintiffs are not seeking to enforce state law, but are attempting to enforce federal requirements." *Id.*; *accord*, *e.g.*, *Norabuena*, 86 N.E.3d at 1207; *Marmol*, 132 F. Supp. 3d at 1370.

Numerous cases demonstrating the non-existence of a state law duty to report to a federal agency dictate the outcome here as well. Plaintiffs allege that the 50 states' laws have such a duty, but plainly they do not. Nor is this litigation a time to invent such a duty. Under *Riegel* and cases applying its reasoning, the parallel state law duty must be established and settled, not something Plaintiffs ask this Court to concoct. Moreover, settled *Erie* principles would stop such a creative effort before it starts.[13] Apart from that, the perils of departing from this parallelism requirement in this context are well-illustrated by the Ninth Circuit's experience in *Stengel v.*

[13] Under *Erie* "it is not the role of a federal court to expand state law in ways not foreshadowed by state precedent." *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 421 (3d Cir. 2002); *Erie R.R. Co. v. Thompkins*, 304 U.S. 64, 78 (1938) ("Except in matters governed by the Federal Constitution or by acts of Congress, the law to be applied in any case is the law of the state.") The court's role instead "is to apply the current law of the jurisdiction, and leave it undisturbed." *Leo v. Kerr-McGee Chem. Corp.*, 37 F.3d 96, 101 (3d Cir. 1994). Thus, when confronted with open questions of state-law liability, federal courts in this Circuit must "opt for the interpretation that *restricts* liability, rather than expands it, until the Supreme Court of [the State] decides differently." *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) (emphasis added; citation omitted); *accord, e.g., Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 254 (3d Cir. 2010); *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 680 (3d Cir. 2002); *Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536, 541-42 (3d Cir. 2001).

Medtronic, Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc). In *Stengel*, over the defendant's vigorous objection, the Ninth Circuit divined a parallel duty to report state law cause of action from Arizona case law. When the claim was litigated in Arizona, however, the state Supreme Court made it clear that no such duty existed:

> [State] law does not permit a manufacturer to satisfy its duty to warn end-user consumers by submitting adverse event reports to the FDA. And conversely, a manufacturer does not breach its duty to warn end users under [state] law by failing to submit adverse event reports to the FDA. … [The duty to warn] has not been extended to require a manufacturer to submit warnings to a governmental regulatory body. … [E]stablished law does not recognize a claim merely for failing to provide something like adverse event reports … to a government agency that has no obligation to relay the information to the patient.

Conklin, 431 P.3d at 577, 579 (citation omitted).

There is no basis to treat the cases in this MDL any differently than *Conklin* or cases aligned with it, and Plaintiffs' failure to report allegations are expressly preempted and should be dismissed.

3. All Warning Claims Based On The Method For Adverse Event Reporting Are Expressly Preempted

In obvious tension with their failure to adequately report allegations, Plaintiffs acknowledge that Allergan *did report* the vast majority of the supposedly "unreported" events to FDA, through an authorized summary reporting method. (CAC ¶¶212-13; PIC ¶¶28, 91-92, 194.) Moreover, FDA expressly authorized this summary reporting method for "Silicone Gel-filled Internal Inflatable Breast Prosthesis … [and] Saline Internal Inflatable Breast Prosthesis." FDA, Summary Reporting of Medical Device Adverse Events (1997), https://web.archive.org/web/20000914063243/http:/www.fda.gov/cdrh/offerlet.htm

l. Nevertheless, as with their inadequate reporting allegations, Plaintiffs attempt to convert this method of reporting into a state law inadequate warning claim and then litigate over *the method* of reporting despite FDA regulations specifically on point.

But as Plaintiffs again are forced to concede, there is no state law duty to warn grounded in a method of reporting to FDA any more than there is such a duty in reporting to FDA in the first instance. The state law duty to warn still runs to the implanting physician and *not* to FDA. Since these failure to warn allegations once again are not anchored in existing state law, there is no parallel state law requirement, and the "method of reporting" warning claims are expressly preempted.

4. All Warning Claims Relating To Reporting Are Impliedly Preempted

In the absence of any recognized state common-law tort cause of action based on FDA-reporting or on a method of the FDA reporting, Plaintiffs are left to rely on the federal statutory scheme as the sole foundation for their alleged duty of care and its breach. That reliance, however, establishes that their reporting claims, no matter how couched or framed, are impliedly preempted as well.

To start with, *Sikkelee,* 907 F.3d at 701, is on point. There, the Third Circuit explained why the implied preemption principles articulated in *Buckman* foreclose failure to report allegations grounded solely on duties contained in federal statutes. The federal statutory scheme here is enforced by the FDA and does not create a standard of care for personal injury plaintiffs. The same was true under the FAA in *Sikkelee*:

> [Plaintiff] argues the District Court erred in granting [defendant] summary judgment on her failure-to-notify-the-FAA claim. ...

> [Defendant] is entitled to summary judgment on this claim. [Plaintiff] has attempted to use a federal duty and standard of care as the basis for this state-law negligence claim. However, ... Congress has not created a federal standard of care for persons injured by defective airplanes. The District Court therefore properly granted summary judgment to [defendant] on this claim.

Sikkelee, 907 F.3d at 716-17 (citing *Buckman*, 531 U.S. at 348, 353) (quotation marks omitted). Here, as in *Sikkelee*, Plaintiffs cannot base their warning claims on the purported breach of a federal duty because there is no such duty running in favor of private plaintiffs. Further, any attempt to recognize such a duty would impermissibly interfere with what the federal statutory scheme requires.

The New Jersey Supreme Court made this very point in *Cornett II*, 211 N.J. 362, 48 A.3d 1041. In that case, the plaintiffs alleged claims based on the "failure to satisfy federal disclosure requirements" concerning off-label use of a Class II medical device. *Id.* at 372. Grounding a claim on federal requirements related to disclosure was, however, deemed impliedly preempted under *Buckman:*

> [R]egardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted.

Id. at 385 (citing *Buckman*, 531 U.S. at 352-53). The reason for invoking implied preemption in this context, as noted previously, is straightforward enough: "[W]arning" allegations that challenged the "adequacy of the information required by the FDA," would "directly interfere with the acknowledged exclusive authority of the FDA to enforce the FDCA" and were impliedly preempted. *Id.* at 389; *see also Gomez v. Bayer Corp.*, 2020 WL 215897, at *12 (N.J. Super. A.D. Jan. 14,

2020) (affirming dismissal of failure-to-report claims as impliedly preempted as "[o]ur Supreme Court has spoken on the subject of federal preemption … involving PMA devices, and we follow its guidance here").

It should come as no surprise, therefore, that courts routinely bring implied preemption principles to bear when, as here, a complaint's allegations reveal a flawed effort to enforce purported federal duties of care. The *D'Addario* court thus also found the same ALCL-related, failure-to-report claims preempted as "fundamentally alleg[ing] fraud-on-the-FDA." 2020 WL 3546750, at *5. After finding that state law did not allow failure-to-report claims, the *Conklin* court did the same and held that failure-to-report claims are impliedly preempted: "Because only federal law, not state law, imposes a duty … to submit adverse event reports to the FDA, [plaintiff's] failure-to-warn claim is impliedly preempted under 21 U.S.C. §337(a)." 431 P.3d at 578 (citing *Buckman*, 531 U.S. at 352-53).

Other cases align and employ the same reasoning in rejecting failure to report claims on implied preemption grounds. *See Sprint Fidelis II*, 623 F.3d at 1205-06 ("Plaintiffs alleged that [defendant] failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations. … [T]hese claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by §337(a) as construed in *Buckman*.") (applying multiple states' laws); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017) ("Applying *Buckman*, [plaintiff's] failure to report theory is impliedly preempted. … Because this theory of liability is based on a duty to file a report with the FDA, it is very much like the 'fraud-on-the FDA' claim the Supreme Court held was impliedly

preempted in *Buckman*.") (applying Florida law); *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) ("[F]ailure to submit reports to the FDA that the FDA requires is arguably a species of fraud on the agency … [and] triggers the same concerns that animated *Buckman*. … [Plaintiff] relies on federal enactments as a critical element in her case. Moreover, this alleged wrong was perpetrated upon the agency, and thus implicates the inherently federal relationship described in *Buckman*.") (applying Michigan law) (quotation marks omitted).

Finally, it should come as no surprise that breast implant device claims are no exception. Thus, in *Brooks*, the court similarly recognized that failure-to-report claims based on federally-created duties of care were impliedly preempted where breast implant devices are involved:

> [T]he MDA would impliedly preempt this theory of recovery. Plaintiffs have not identified any state law that required [defendant] to report adverse events to the FDA. Accordingly, like their other claims relating to FDA reporting, plaintiffs are not seeking to enforce state law, but are attempting to enforce federal requirements. The MDA impliedly preempts this theory of recovery.

2019 WL 4628264, at *6 (citation omitted). *Brooks* also is not alone. *See Vieira*, 392 F. Supp. 3d at 1130-31 (breast implant plaintiff "could not avoid preemption" where the relevant state "does not recognize such claims"); *Jacob Cal.*, 393 F. Supp. 3d at 925 (same).[14]

[14] And, once again, the list goes on. *E.g.* ***Second Circuit*****:** *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 202 (E.D.N.Y. 2015) ("since Plaintiff's failure to warn claim is predicated on Defendant's alleged failure to provide the required reports to the FDA, authority to enforce that claim rests with the FDA"). ***Third Circuit*****:** *Chester*, 2017 WL 751424, at *10 ("claims based upon such violations are impliedly

One cannot read Plaintiffs' complaints—laden with myriad references to the FDCA, FDA, and FDA regulations—and reach any conclusion other than purported FDCA violations are "a critical element" of all their warning claims, thereby mandating that implied preemption be applied.

C. Plaintiffs' Claims Alleging That Allergan Should Have Submitted A "Changes Being Effected" Supplement For Its Warnings Are Expressly Preempted

Plaintiffs also allege that after Allergan learned more about the risk of ALCL, it was required to submit a PMA supplement strengthening its warnings through FDA's "changes being effected" ("CBE") regulation, 21 C.F.R. §814.39(d). (PIC ¶¶64, 189.) Claims based on these allegations are expressly preempted because they purport to impose a mandatory state law duty where federal law does not. A state

---

preempted as impermissible attempts to enforce FDA reporting requirements under" *Buckman*). ***Fourth Circuit*:** *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 492 (W.D.N.C. 2017) ("A requirement to report adverse events exists under the FDCA, and plaintiff's cause of action is being brought because ... defendants allegedly failed to meet these reporting requirements. Accordingly, the plaintiff's failure-to-warn claim is preempted.") (citing *Buckman*). ***Tenth Circuit*:** *Littlebear v. Advanced Bionics*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012) ("[a]ll claims predicated on the failure to comply with adverse event reporting requirements are impliedly pre-empted"). ***Georgia*:** *Latimer*, 2015 WL 5222644, at *9 (quoting and following *Littlebear*). ***Kentucky*:** *Cales*, 2014 WL 6600018, at *10 (claims "predicated on . . . an alleged failure to submit adverse-event reports to the FDA would be impliedly preempted under *Buckman*"). ***Massachusetts*:** *Phillips v. Medtronic, Inc.*, 2012 WL 3641487, at *10 (Mass. Super. July 10, 2012) (a "claim based on failure to report adverse events ... is impliedly preempted because it is premised solely on a duty created by the MDA which did not exist in the common law"). ***New York*:** *Lake v. Kardjian*, 874 N.Y.S.2d 751, 755 (N.Y. Sup. 2008) (failure-to-report claims "are impliedly preempted by federal law, because enforcement of the FDCA, including the MDA, is the sole province of the federal government").

law duty that would require something different from, or in addition to, what federal law requires is expressly preempted, as *Riegel* and its progeny make abundantly clear.

Here, Plaintiffs' proposed mandatory duty to supplement plainly is different. The CBE regulation is permissive, not mandatory. It provides that changes "reflect[ing] newly acquired information that enhances the safety of the device … *may be* placed into effect by the applicant prior to the receipt … of a written FDA order approving the PMA supplement." *Id.* (emphasis added). Further, CBE regulation's use of the permissive "may" stands in sharp contrast to the same regulation's use of the obligatory "shall" for other types of PMA supplements.[15] *See Lopez v. Davis*, 531 U.S. 230, 231 (2001) ("use of the permissive 'may' contrasts with Congress' use of a mandatory 'shall' elsewhere in" same statutory section); *Jahn v. Comm'r, IRS*, 392 F. App'x 949, 950 (3d Cir. 2010) (distinguishing between mandatory "shall" and permissive "may"). Any effort to convert the discretionary duty to supplement into a mandatory one would impermissibly alter the regulation's wording and violate accepted principles of construction as well.

As the Ninth Circuit *en banc* majority also confirmed in *Stengel*, the permissive nature of the CBE regulation is determinative in the preemption analysis. In that case, the court confronted a similar claim that the defendant should have made post-sale warnings that were permitted, but not required, under the applicable

[15] *See* 21 C.F.R. §814.39(a) ("an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device"); 21 C.F.R. §814.39(e)(2) (a "30-day PMA supplement shall follow the instructions" of FDA).

regulations—and held that such a claim was expressly preempted. *Stengel*, 704 F.3d at 1234 ("Regulations issued by [FDA] permitted [defendant] to issue such post-sale warnings, even without receiving prior approval from FDA, but those regulations did not require such warnings. *See* 21 C.F.R. §814.39(d). As a result, any attempt to predicate [plaintiffs'] claim on an alleged state law duty to warn doctors directly would have been expressly preempted ….". *Stengel*, 704 F.3d at 1234 (Watford, J., concurring).

The rationale for this result, as noted, is self-evident: the state-law-breach of duty claim would *require* the manufacturer to have provided a warning where the federal regulation would not. Courts agree that express preemption must take hold in such circumstances. *See Sprint Fidelis II*, 623 F.3d at 1205 ("[e]ven if federal law *allowed* [defendant] to provide additional warnings, as Plaintiffs alleged, any state law *imposing* an additional requirement is preempted by §360k") (emphasis original); *Riley*, 625 F. Supp. 2d at 783 ("[A] failure-to-warn claim cannot parallel §814.39(d) because §814.39(d) merely *permits* a device manufacturer to make a temporary change to a label whereas a successful failure-to-warn claim would *require* such a change.") (emphasis original); *McGookin v. Guidant Corp.*, 942 N.E.2d 831, 838 (Ind. App. 2011) (preempting mandatory CBE claim; "We cannot imagine a plainer example of an attempt to impose a standard of care in addition to the FDA's specific federal requirements."). Permitting such a claim would restrict "[t]he flexibility inherent" in FDA regulations and thus necessarily "impose requirements 'different from, or in addition to' those under federal law." *In re*

Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) ("*Sprint Fidelis I*").

In sum, Plaintiffs' efforts to fashion a state law duty based on allegations that Allergan was required to supplement its warnings under the CBE regulation are expressly preempted because they are a transparent attempt to change what federal law requires. No state law duty can be employed to accomplish that result in this context and these claims should be dismissed.

D. Plaintiffs' Claims Challenging Allergan's Post-Sale Clinical Studies Are Expressly Preempted

Plaintiffs also assert that Allergan failed to conduct clinical studies after the FDA approved its PMAs. As a result, Plaintiffs further allege that they and their physicians were not warned about the possible risk of ALCL. Plaintiffs allege that Allergan did not comply with FDA's post-approval study requirements regarding long-term performance of the approved devices. (CAC ¶¶227-254; PIC ¶¶6, 53, 77(f), 169, 186, 246.) But there is no state law duty that required Allergan to undertake the studies—that requirement existed solely by virtue of FDA's regulatory oversight and approval of Allergan's PMA. As with failure to report warning claims, therefore, "[w]ithout a freestanding basis in state law," allegations of "failure to 'conduct a study'" also are expressly preempted. *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 747 (D. Md. 2015). Likewise, in *Brooks*, no state-law duty existed to report negative study results about breast implants to the FDA. 2019 WL 4628264, at *6. It was "far too speculative" to "assume that plaintiffs' physicians would have accessed [adverse event] information and relied on it." *Id.*

For these same reasons, "failure to conduct a study" allegations were held preempted in the only other current MDL involving a PMA device. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 401 F. Supp. 3d 538, 562 (D. Md. 2019) ("[P]laintiffs … pointed to no state-law duty that predated the MDA that would similarly require [defendant] to undertake this research."). And, similar allegations were also preempted in a recent breast implant case. *Ebrahimi*, 2017 WL 4128976, at *5 (preempting allegations that the defendant failed to properly conduct a large post-approval study when the actual number of enrolled patients was fewer than the number prescribed by the FDA, because there is "no parallel state-law duty to conduct post-approval 'follow-through studies.'").

The same result should follow here and the failure to conduct a study claims are expressly preempted and should be dismissed.

E. Plaintiffs' "Manufacturing Defect" Claims Attacking Allergan's PMA-Approved Manufacturing Process Are Expressly Preempted

The Master Complaints contain a variety of allegations styled as "manufacturing defects" that supposedly parallel recognized state law causes of action founded on such defects. Manufacturing defects, when properly alleged, conceivably can fit through the narrow gap between express and implied preemption. Where a device is not manufactured in accordance with approved device specifications, there can be a violation of the federal statute. And, where established state law recognizes product liability claims for products that deviate from the norm, the recognized parallelism exists. Here, however, Plaintiffs efforts to fit their "manufacturing defect" claims in the gap fail for two reasons. First, there are no

allegations that Allergan's breast implants deviated from their FDA-approved design. Second, on analysis, Plaintiffs' allegations are not attacking a deviation from the approved design but rather the design itself. Either way, preemption applies and Plaintiffs' claims fail.

1. Plaintiffs Do Not Allege Any Deviation From FDA Manufacturing Specifications So Express Preemption Applies

Plaintiffs allege that Allergan's devices generally were "adulterated" because of Allergan's use of salt-loss texturing. (*E.g.*, CAC ¶190, PIC ¶114.) Plaintiffs also allege that Allergan did not properly "validate" or otherwise oversee that process, leading to the manufacture of implants that had variable texture. (CAC ¶14; PIC ¶¶118-19, 123 129, 132, 149). But *nowhere* do they allege that any device deviated from an FDA-approved manufacturing process and attendant FDA-approved device specifications. That is fatal to their manufacturing defect claims.

FDA's premarket approval requires the approved device to be manufactured "with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323. Thus, as a broad rule, "allegations of strict products liability based on manufacturing defect … are precisely the type of claims the MDA sought to preempt." *Williams v. Cyberonics, Inc.*, 388 F. App'x at 171. "To survive preemption, manufacturing defect claims must allege that the device was not made in accordance with the specifications approved by the FDA." *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 493 (W.D.N.C. 2017). Thus, where plaintiffs fail to plead "how [the device] deviated from the FDA approved manufacturing process" and nowhere "specify a causal connection between the failure of the specific

manufacturing process and the specific defect" their manufacturing defect claims are preempted. *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011).

Judge Shipp's recent decision in a nearly identical breast implant case, *D'Addario*, 2020 WL 3546750, illustrates the proper analysis for manufacturing defect allegations. There, plaintiffs alleged that the defendants' breast implants caused them to develop ALCL. *Id.* at *1. Among other things, they alleged that the implants were "manufactured in a non-conforming manner because they contained a graham-negative biofilm/endotoxin released from the surface of the textured surface which stimulates lymphocytes … and that these bacteria stimulating lymphocytes caused" her disease. *Id.* at *4. Judge Shipp found that the plaintiffs "d[id] not … allege that *the FDA required* the exclusion of this endotoxin." *Id.* (emphasis added). Thus, with no "properly identified" federal requirement supporting the purported manufacturing defect claim, it was preempted. *Id.* Moreover, Judge Shipp continued, "broad[]" allegations that defendants "failed to adhere to numerous federal specifications" could not save the claim, given the plaintiffs' failure to state how any regulatory violation "resulted in the presence of lymphocytes in her implants." *Id.*

Likewise, applying Florida law, the Eleventh Circuit made the same distinction between product liability claims alleging manufacturing as opposed to design defects:

> This distinction between "aberrational" defects and defects occurring throughout an entire line of products is frequently used in tort law to separate defects of manufacture from those of design. ... Stated another way, the distinction is between an unintended configuration, and an

> intended configuration that may produce unintended and unwanted results.

Harduvel v. General Dynamics Corp., 878 F.2d 1311, 1317 (11th Cir. 1989); *see Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334, 1344 (S.D. Fla. 2019) (following *Harduvel*), *appeal docketed*, No. 20-10900 (11th Cir. Mar. 9, 2020); *Miller v. United Techs. Corp.*, 660 A.2d 810, 846 (Conn. 1995) (same); *Nicholson v. Pickett*, 2016 WL 854370, at *20 (M.D. Ala. March 4, 2016) (same); *Roll v. Tracor, Inc.*, 102 F. Supp. 2d 1200, 1202 (D. Nev. 2000) (same); *Oliver v. Oshkosh Truck Corp.*, 911 F. Supp. 1161, 1175 (E.D. Wis. 1996) (same), *aff'd*, 96 F.3d 992 (7th Cir. 1996).[16]

In sum, without express allegations showing how Allergan's devices, as manufactured, deviated from their FDA-approved designs, no manufacturing defect allegation can survive preemption. Plaintiffs' manufacturing defect claims must be dismissed for this reason. *See Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *7 (D.N.J. March 5, 2009) ("As [plaintiff] has not pointed to a defect or a deviation

[16] By way of further example, the same is true in California. *See Hannan v. Boston Sci. Corp.*, 2020 WL 2128841, at *5 (N.D. Cal. May 5, 2020) (granting summary judgment for defendants on manufacturing defect claims when "incorrect manufacturing processes that plaintiffs identify … are indicative of a flaw in the design of an entire line of products rather than one product differing from other ostensibly identical units"); *In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 301, 315 (Cal. App. 2002) ("[T]hat simultaneously manufactured [units] were subject to different standards at different production lines, due to the status of the manufacturer's research and development, where scientific knowledge was inconclusive … does not require that some items must be deemed defective under a manufacturing defect approach. Rather, such arguments actually deal with design defect evidence ….").

from the FDA-reviewed … manufacturing specifications regarding the [device] implanted in him, the Court dismisses [his] manufacturing defect claim."); *accord Chester*, 2017 WL 751424, at *8; *Mendez v. Shah*, 94 F. Supp. 3d 633, 638-39 (D.N.J. 2015); *Morton*, 2015 WL 12839493, at *5; *Becker v. Smith & Nephew, Inc.*, 2015 WL 268857, at *3 (D.N.J. Jan. 20, 2015); *Smith*, 2013 WL 1108555, at *9.

2. Plaintiffs' Allegations That All Textured Breast Implants Are Defective As Manufactured Are Expressly Preempted

Plaintiffs' "manufacturing defect" allegations also make clear that they are not really claiming that Allergan's implants deviated from the norm. Far from it, their allegations attack the norm directly and plainly. That is, Plaintiffs' allegations are aimed at the processes by which all of Allergan's devices are manufactured. That is nothing more or less than a design defect allegation disguised in "manufacturing defect" clothing. Case law again supports the application of preemption in this instance.

To begin with, claims that challenge the design and processes by which all of the PMA-market approved medical devices are manufactured, as Plaintiffs' claims do here, are an effort to change what federal regulation commands—the quintessentially preempted claim. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 580-81 (4th Cir. 2012) ("A common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by *Riegel*.").

In addition, Plaintiffs' attack on the *process* by which all the devices are manufactured is a semantic game that cannot be resorted to avoid preemption. The

Third Circuit's recent decision in *Coba v. Ford Motor Co.*, 932 F.3d 114 (3d Cir. 2019) (applying New Jersey law) recognized as much when the plaintiffs there tried to disguise what was, in effect, a design defect—by calling it a manufacturing defect—in a breach of warranty case. The Court noted that the claims, as alleged, "ha[d] all the trappings of a design defect," since plaintiffs: (1) did not allege "low quality," but rather the defendant's decision to use a particular process in "constructing" the product; and (2) "alleg[ed] that '[a]ll' of the [products] manufactured this way suffer from a 'common' issue." *Id.* at 123.[17] The allegations here align with *Coba* in every material respect. Plaintiffs attack the process by which the devices are made—a charge aimed at the devices' design, not the way a particular device was manufactured.

Here, the devices produced by Allergan's design process have not "deviated from" the FDA approved "specifications, formulae, or performance standards" and are not at variance from "otherwise identical units," N.J.S.A. 2A:58C-2, and Plaintiffs do not claim that is the case. Rather, each device is exactly what the FDA required in its PMA approval. Plaintiffs' "manufacturing defect" allegations therefore must be preempted just as any other effort to impose state law liability over a PMA-approved design would be. Dismissal again is required.

[17] In the *Agent Orange* MDL, the Second Circuit adopted the same reasoning: "plaintiffs allege[d] a defective process, not that the process used was somehow erroneously applied. They therefore allege a design defect." *In re Agent Orange Prod. Liab. Litig.*, 517 F.3d 76, 92 n.15 (2d Cir. 2008) (applying laws of multiple jurisdictions).

F. Plaintiffs' Claims Based In Whole Or In Part On "Adulteration" Are Impliedly Preempted

Plaintiffs have couched their defective device allegations in "adulteration" terminology but that linguistic choice does not avoid preemption. Instead, by relying on "adulteration," they again have made FDCA standards "a critical element" of their claims, in violation of the preemptive principles set forth in *Buckman*, 531 U.S. at 353. Whether a defendant's products are "'adulterated' under … the FDCA" is a "matter[] rest[ing] within the enforcement authority of the FDA, not this Court." *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting district court). "[A] conclusion that a particular ... product is 'adulterated,' in the abstract, means little other than that FDA could choose to initiate enforcement proceedings." *Comty. Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987). That is why, moreover, that the Third Circuit has mandated preemption in these circumstances:

> [V]iolations of the FDCA do not create private rights of action. Thus, only the government has a right to take action with respect to adulterated products. Additionally, … to the extent [plaintiff's] adulteration claim is derivative of her other claims …, she cannot overcome a finding of preemption merely by claiming that the product was adulterated.

Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994) (citations omitted); *see also Riegel*, 552 U.S. at 329 ("adulteration and misbranding claims are pre-empted when they have the effect of establishing a substantive requirement for a specific device") (citation and quotation marks omitted).

In this instance, "adulteration" allegations, like Plaintiffs', complaining of "noncompliance with the technical, administrative details of the FDA's complex regulatory scheme" are impliedly preempted because they "would not give rise to

such tort liability if the FDCA or the regulatory regime created pursuant to it had never existed." *Barnes v. Howmedica Osteonics Corp.*, 2010 WL 11565343, at *15 (N.D. Ala. Dec. 14, 2010); *see also Martin v. Medtronic, Inc.*, 2017 WL 825410, at *7 (E.D. Cal. Feb. 24, 2017) (finding "'adulteration'-based claims are incongruous with the common law and thus impliedly preempted because they entirely rest on defendants' purported violations of the FDA's CGMPs"). "Any derivative claim that the [device] was adulterated as a result of" an FDCA violation "is a disguised claim to privately enforce the federal law, prohibited under 21 U.S.C. §337(a)." *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 685 n.20 (W.D. Ky. 2013).[18]

De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) is on point as well. There, the plaintiff alleged "adulteration" as a "manufacturing" defect based on the defendant's "failing to adequately *document*" a "validation protocol"—"not in the actual manufacture of the product." *Id.* at 1095 (emphasis

[18] *See*, *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011) ("claims premised on Plaintiffs' derivative assertion that the … device … was 'adulterated' or 'misbranded' … are also preempted"); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 660 (S.D. Tex. 2010) (the FDCA "explicitly precludes private enforcement of federal laws regarding 'adulterated' devices"); *Cornwell v. Stryker Corp.*, 2010 WL 4641112, at *4 (D. Idaho Nov. 1, 2010) ("To the extent Plaintiff's parallel claim is based on a theory the medical device implanted in Plaintiff was 'adulterated' such claim must also be dismissed as there is no private right of action"); *Sprint Fidelis I*, 592 F. Supp. 2d at 1162 ("Because Plaintiffs manufacturing-defect claims are preempted, this derivative [adulteration] assertion is also preempted.") (following *Gile*; other citations omitted); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (plaintiff's claims are "not saved [from preemption] merely by being recast as violations of the federal adulteration and misbranding statutes").

original). That claim was impliedly preempted because it did not resemble a common-law manufacturing defect:

> [Plaintiff] must allege that the irregularities … resulted in a manufacturing defect that caused her injuries. In other words, she cannot state a claim based solely on [defendant's] adulteration of certain … devices, since any such claim would "exist solely by virtue of the [MDA] ... requirements." [Plaintiff] has failed to allege such a manufacturing defect.

Id. at 1094-95 (citing *Buckman*, 531 U.S. at 353). As a result, the claimed FDCA "irregularities" did not create "a breach of any parallel state law duties that could escape implied preemption." *Id.* at 1095.

In this case, Plaintiffs' "adulteration" allegations do not resemble any common law manufacturing defect claim and exist solely by virtue of FDA requirements. All their allegations relying on "adulteration" accordingly are preempted.

G. Plaintiffs' Negligence *Per Se* Claims Are Impliedly Preempted

Plaintiffs' negligence *per se* claims boil down to allegations that Allergan breached duties solely created under the FDCA. These are no different from the kinds of claims that numerous courts around the country have rejected on preemption grounds. The same result should follow here.

By definition, a negligence *per se* claim takes "a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man." *Ries v. Nat'l R.R. Passenger Corp.*, 960 F.2d 1156, 1158 (3d Cir. 1992) (quoting Restatement (Second) of Torts §288B(1) (1965)). *Accord Sprint Fidelis I*, 592 F. Supp. 2d at 1163. Where negligence *per se* is based

on alleged FDCA violations, the FDCA becomes "a critical element in [Plaintiffs'] case" and the "duty" thereby defined "exist[s] solely by virtue of the [MDA] ... requirements." *Buckman*, 531 U.S. at 353.

In this type of litigation, therefore, negligence *per se* claims are no more than improper attempts at private FDCA enforcement:

> [Plaintiffs'] interpretation of *per se* liability would allow private plaintiffs to recover for violations of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government. Plaintiffs' theory would undermine section §337(a) by establishing a private, state-law cause of action for violations of the FDCA…. We do not believe the concept of *per se* liability supports such a result.

In re Orthopedic Bone Screw Prod. Liab. Litig., 193 F.3d 781, 791 (3d Cir. 1999) (citation and footnote omitted); *see also Talley v. Danek Med., Inc.*, 179 F.3d 154, 158 (4th Cir. 1999) (holding negligence *per se* claim preempted pre-*Buckman*) (applying Virginia law) ("[T]he negligence *per se* doctrine ... is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute.").

In *Cornett II*, the New Jersey Supreme Court also applied *Buckman* to affirm dismissal of a negligence *per se* claim, holding that the elements of "traditional state law cause[s] of action" exist "with no reference to federal requirements as the measure of the reasonableness or wrongfulness of the manufacturer's conduct." *Cornett II*, 211 N.J. at 385, 48 A.3d at 1054. Since negligence *per se* "depend[ed] on the alleged violation of a federal requirement," it was "functionally equivalent to

a claim grounded solely on the federal violation" and thus impliedly preempted. *Id.* (*Buckman* citations omitted).[19]

In *Brooks*, after looking at similar claims involving breast implants, the court also rejected the plaintiff's "roundabout way of asserting a negligence *per se* claim based on a violation of the FDCA." 2019 WL 4628264, at *7. As the court noted, "negligence *per se* is limited to violations of a statute where the legislature intended to create an individual right of action," and "Congress did not intend a private federal remedy for violations of the FDCA." *Id.* at *5 n.5 (citations and quotation marks omitted). The plaintiff in *Brooks* could not "conjure up a parallel state claim that survives implied preemption" by "argu[ing] that [defendant] violated state law *because* it violated federal law. *Id.* at *7 (emphasis original). In *Rowe*, another breast-implant-related negligence *per se* claim was "impliedly preempted" as "the sort of claim addressed by *Buckman*, in which [the plaintiff] is suing because [the defendant] violated federal regulations." 297 F. Supp. 3d at 1298.

And the MDL court in *In re Bard IVC Filters* considered the same sort of negligence *per se* claims alleged here—"misbranding … false and misleading statements … failing to notify FDA when the [devices] were no longer safe and

[19] *Cornett II* thus affirmed the Appellate Division, which had held that ostensibly state-law claims "had to be preempted [under *Buckman*], because they were in effect no more than *per se* claims for violation of a federal requirement" and were therefore "distinguishable from state-law causes of actions that parallel federal safety requirements." *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 394, 998 A.2d 543 (A.D. 2010) ("*Cornett I*"), *aff'd*, 211 N.J. 362, 48 A.3d 1041 (N.J. 2012).

effective, failing to recall the devices, and not maintaining accurate adverse event reports"—and foreclosed those claims on implied preemption grounds:

> While it is true that courts generally have allowed a negligence *per se* claim based on violation of a statute that does not expressly provide for a private right of action, the plain language of §337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails.... [A]llowing the claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations."

2018 WL 1256768, at *8-9 (D. Ariz. March 12, 2018) (applying Georgia law).[20]

Most simply put, FDCA-based negligence *per se* claims are indisputably preempted because they "arise[] directly and wholly derivatively from the violation of federal law." *Norman*, 2016 WL 4007547, at *5; *Green v. Medtronic, Inc.*, 2019 WL 7631397, at *15 (N.D. Ga. Dec. 31, 2019).[21] "[P]laintiffs' claim of negligence

---

[20] *See In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 4356638, at *2-3 (D. Ariz. Sept. 12, 2018) (same applying Wisconsin law); *In re Bard IVC Filters Prod. Liab. Litig.*, 2017 WL 5625548, at *8-10 (D. Ariz. Nov. 22, 2017) (same applying Georgia law).

[21] *See*, *e.g.*, *Hayes v. Endologix, Inc.*, ___ F. Supp. 3d ___, 2020 WL 1624022, at *4 (E.D. Ky. March 26, 2020) ("negligence *per se* … does not escape preemption"); *Sharp v. St. Jude Med., S.C., Inc.*, 396 F. Supp. 3d 1250, 1261 (N.D. Ga. 2019) ("Plaintiff's negligence *per se* claim is impliedly preempted, as [it] uses Defendants' alleged violation of federal law to substantiate the existence of a state tort claim"); *Mullins v. Ethicon, Inc.*, 2017 WL 275452, at *2 (S.D.W. Va. Jan. 19, 2017) ("plaintiff cannot properly state a negligence *per se* claim under the [FDCA]"); *Perdue v. Wyeth Pharmaceuticals, Inc.*, 209 F. Supp. 3d 847, 851 (E.D.N.C. 2016) ("plaintiff's claim of negligence *per se* based upon a violation of the FDCA is impliedly preempted under *Buckman*"); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) ("negligence *per se* … claims are impliedly preempted under *Buckman*"); *Thibodeau v. Cochlear Ltd.*, 2014 WL 3700868, at *5 (D. Ariz. July 25, 2014) (negligence *per se* "impliedly preempted because it is based directly on a violation of federal law"); *Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1071 (W.D. Mo. 2014) (negligence *per se* "is impliedly preempted because the

per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law." *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *8 (N.D. Ga. Aug. 19, 2011); *Grant v. Corin Group PLC*, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016) (same). "While courts have generally allowed a negligence *per se* claim based on violation of a federal statute, the plain language of §337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails." *Dunbar v. Medtronic, Inc.*, 2014 WL 3056026, at *5 (C.D. Cal. June 25, 2014).

Plaintiffs' negligence per se claims are no different and deserve the same fate.

H. Plaintiffs' Claims Involving Allergan's Class II Style 153 And McGhan RTV Implants Are Preempted

Plaintiffs further allege that some patients received two specific types of devices, which were cleared by FDA for sale: (1) McGhan Textured Breast Implant, Style 153; and (2) McGhan RTV® Saline-Filled Mammary Implant. (*See* discussion

---

applicable standards of care rely on the MDA and, therefore, the existence of this claim exists solely by virtue of the federal requirements"); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 705-06 (S.D. Tex. 2014) (plaintiff "cannot avoid *Buckman*'s implied preemption holding" by asserting negligence *per se*); *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 1000 (D. Ariz. 2013) ("a claim for negligence that is premised solely on a manufacturer's violation of a federal standard—here the FDCA and MDA—is impliedly preempted"); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1152 (D. Minn. 2011) ("a claim of negligence *per se* cannot be based on a violation of the FDCA … under *Buckman*"); *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (negligence *per se* claim preempted; "Plaintiff cannot avoid preemption simply by recasting her claims to allege violations of the FDCA"), *adopted*, 2010 WL 2543570 (D. Colo. June 22, 2010); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) ("many courts have held plaintiffs cannot seek to enforce [the FDCA] through negligence *per se* tort actions").

supra at 12-13.) But investigational devices (Style 153) cleared as safe and effective by the FDA are fully protected from state tort law claims by PMA preemption. So, too, are reclassified devices (McGhan RTV®) after the date of their reclassification to PMA.[22] Further, the implied preemption arguments above apply equally to all FDA-regulated medical devices, regardless of device classification—*Buckman*, 531 U.S. at 345-46, involved a §510(k) device—and independently require that Plaintiffs' claims be dismissed.

1. PMA Preemption Applies To IDE Medical Devices

"To obtain the data to support an application for premarket approval, a manufacturer may use the device in clinical trials under active FDA supervision pursuant to the FDCA's Investigational Device Exemption ("IDE") provisions and accompanying federal regulations. Premarket approval will be granted only if the IDE investigation proves the device is sufficiently safe and effective." *Orthopedic Bone Screw*, 193 F.3d at 786 (citing 21 U.S.C. §360j(g)). "In granting IDE approval, the FDA imposes detailed requirements on the design, manufacture, and warnings for Class III devices as well as the conduct of the clinical investigation." *Robinson v. Endovascular Techs., Inc.*, 119 Cal. Rptr. 3d 158, 164 (Cal. App. 2010). In fact, FDA's regulatory scheme, "impos[es] over 150 separately numbered regulations on IDE devices." *Burgos v. Satiety, Inc.*, 2010 WL 4907764, at *7-8 (E.D.N.Y. Nov. 30, 2010) (citing 21 C.F.R. §812).

[22] To the extent any Plaintiffs received McGhan RTV® implants before that device's May 2000 PMA, their claims would not be subject to express preemption, unless they seek changes to FDA requirements that could only arise after the PMA date.

Given FDA's close oversight of IDE products, the Third Circuit has recognized that claims involving IDE devices are preempted. *See Gile*, 22 F.3d at 545 ("[S]tate tort law invoked to challenge the safety or effectiveness of a [device] which is part of an FDA investigation is federally preempted."). Preemption is required because "a jury determination that the device is not sufficiently safe and effective would not only be contrary to the experimental purposes of the exemption, but, more important, would directly conflict with FDA's contrasting judgment. *Id.*

Other circuits are in accord. *See, e.g.*, *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1247-48 (7th Cir. 1997) (product liability "claims would defeat the purpose of the investigational device exemption, which is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use") (citation and quotation marks omitted); *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997) ("the application and approval process under the IDE is device specific"); *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995) ("The point of the experiment is to find out *whether* the design is safe and effective. … [S]tate tort claims would impose requirements … that are, certainly, additional to those imposed by the MDA scheme."); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333-34 (7th Cir. 1992) (affirming dismissal of personal injury action involving an IDE device, on preemption grounds).

Indeed, almost every court since *Riegel* to consider express preemption in the IDE context has recognized the same broad scope of preemption applicable to PMA devices. *See, e.g.*, *Russell*, 2018 WL 5851101, at *4-5 ("state law challenges to

devices granted IDE for clinical testing were preempted by federal law"; "*Riegel* offers the greatest similarity" to IDEs); *Bush v. Goren*, 2014 WL 4160245, at *7 (Mich. App. Aug. 21, 2014) ("Like PMA applications, IDE applications are focused on safety and efficacy and specific to individual devices.") (citation omitted); *accord Parks v. Howmedica Osteonics Corp.*, 2016 WL 7220707, at *6-8 (M.D. Fla. March 11, 2016); *Grant*, 2016 WL 4447523, at *3-5; *Day v. Howmedica Osteonics Corp.*, 2015 WL 13469348, at *4-5 (D. Colo. Dec. 24, 2015); *Killen v. Stryker Spine*, 2012 WL 4498865, at *1 (W.D. Pa. Sept. 28, 2012).

This precedent again includes cases involving Allergan's investigational breast implant devices. *See Dorsey v. Allergan, Inc.*, 2009 WL 703290 (M.D. Tenn. March 11, 2009). ("Unquestionably, state products liability claims with respect to an FDA approved investigational device are preempted" because to hold otherwise "would thwart the goals of safety and innovation.") (citation and quotation marks omitted); *Williams v. Allergan USA, Inc.*, 2009 WL 3294873, at *2-3 (D. Ariz. Oct. 14, 2009) ("FDA has established extensive requirements applicable to" IDE devices).

For these reasons, the preemption analysis for Plaintiffs who received the Style 153 investigational device is no different than it is for Plaintiffs who received PMA devices. In all cases, their claims are preempted.

2. PMA Preemption Applies To Reclassified PMA Medical Devices

The Allergan RTV® breast implant device, while originally approved as "substantially equivalent" under Section 510(k) in the mid-1980s, was required by FDA to be resubmitted as a PMA device in November 1999, and received pre-market

approval in May 2000. Since liability "hinges upon" whether the device was defective "at the time the alleged tort was committed," the PMA in place *at that time* is what matters. *Sprint Fidelis I*, 592 F. Supp. 2d at 556 (internal citation and quotation marks omitted). Thus, the claims of plaintiffs who had post-May 2000 RTV® implants are expressly preempted for all of the reasons previously stated.

PMA preemption thus was applied on similar facts in *Starks v. Coloplast Corp.*, 2014 WL 617130 (E.D. Pa. Feb. 18, 2014), where (as with the RTV®) an implanted device was first cleared under §510(k), but then successfully resubmitted to FDA under the PMA process. *Id.* at *4 n.8. The in-force PMA controlled:

> The §510(k) clearance of a medical device's predicate or its components, however, does not change the preemptive effect of premarket approval of the current device. The ... implant received premarket approval ..., and that premarket approval has preemptive effect.

Id. (citations omitted). As discussed, whether a device enjoys PMA approval when used for a particular patient governs the availability of preemption. Thus, PMA preemption bars all manufacturing defect claims made by plaintiffs receiving RTV® implants after May 2000. To the extent that any claims—such as post-sale duty to warn—would require a modification after the device received PMA, those claims are preempted as well. *See Brooks v. Howmedica, Inc.*, 273 F.3d 785, 789 n.5 (8th Cir. 2001) (PMA preemption applies to device reclassified to §510(k) "after" plaintiff was "exposed") (en banc); *Allen v. Zimmer Holdings, Inc.*, 2015 WL 6637232, at *2 (D. Nev. Oct. 30, 2015) (later reclassification "does not affect the analysis"); *Thompson v. Depuy Orthopaedics, Inc.*, 2015 WL 7888387, at *8 (S.D.

Ohio Dec. 4, 2015) (no preemption where a PMA device had been downclassified to §510(k) prior to plaintiff's use); *Scott v. Pfizer Inc.*, 249 F.R.D. 248, 254 n.8 (E.D. Tex. 2008) (later "reclassification has no bearing on" preemption).

V. CONCLUSION

For the foregoing reasons, this Court should dismiss all claims in the Master Complaints related to devices that received FDA approval through the PMA process and also devices that (1) FDA reclassified to PMA-status, or (2) were the subject of research during the PMA process under the IDE, but never approved.

Dated: August 7, 2020

Respectfully submitted,

REED SMITH LLP

By: */s/ Melissa A. Geist*
Melissa A. Geist

Attorneys for Defendants
Allergan Inc. and Allergan USA, Inc.